LIQUID ELEMENTAL DIET

BACKGROUND OF THE INVENTION

1. Field

This disclosure is concerned with a nutritionally balanced food composition and specifically with a ready-to-use liquid elemental diet which is non-browning at elevated temperatures.

2. Prior Art

Nutritionally balanced diet compositions have been known and available for many years. Typically, such compositions include carbohydrate, protein and lipid components as well as vitamins and minerals. In the case of so-called elemental diet compositions, the protein component may be made available in a nutritionally desirable balance of low molecular weight peptides and/or amino acids. Unfortunately, when amino acids and carbohydrates are combined in an aqueous solution, these components have a tendency, especially with time and at elevated temperatures, to result in a brownish solution and form undesirable by-products due to the well known Maillard reaction(s).

It is well known that this generally undesirable color change (which includes the formation of somewhat toxic melanoidin end products) is associated principally with the pH of the carbohydrate-amino acid solution. The pH controls the chemical state of the reducing end groups of available carbohydrates and the amine groups of the amino acids or peptides. Inhibition of Maillard browning reactions may be accomplished by (1) maintaining the solution pH below the isoelectric points of the amino acids and peptides (e.g. less than about 4.2); (2) keeping the solution temperature as low as possible during processing and storage; and/or (3) by increasing the mean distance between reactants (e.g. a 3.1% solution of amino acids is less likely than a 6.2% solution to form solution browning reaction products with glucose.

In general it has been known that the undesirable products and coloring of the Maillard reactions can be avoided or minimized by maintaining the pH below about 4.5. See, for example, U.S. Pat. No. 4,144,357 which summarizes some of the earlier observations in this area. See also the disclosures in U.s. Pat. No. 2,426,639 showing various ways to assure a low pH while still keeping a food product palatable.

Even though it has been known that the Maillard reaction(s) could be avoided or minimized by maintaining a relatively low pH, it has been difficult for elemental diet manufacturers to provide such diets in a ready-to-use, liquid form because of the known lack of stability of lipid emulsions in the pH range needed to avoid the Maillard reactions. Because of this, until very recently (e.g. the recently announced CRITICARE ready-to-use liquid elemental diet, Mead-Johnson Corp.), manufacturers have provided liquid elemental diets in a dry form, typically in a foil packet which must be mixed with water just prior to use. Aside from the obvious inconvenience of having to mix a dry powder prior to use, it can be appreciated that the very act of mixing raises possibilities of contamination which can be of concern vis-a-vis the environment (i.e. hospital patients) in which liquid elemental diets are often used.

Quite surprisingly, it has been found that stable, heat-sterilizable elemental diet compositions can now be prepared in a liquid form. The product, being ready-to-use, avoids the disadvantages associated with elemental diets in dry form. Details of the discovery are described below.

SUMMARY OF THE INVENTION

The liquid elemental diet composition of this invention comprises an aqueous combination of carbohydrate, amino acid, and lipid components, the combination being at a pH ranging from about 3.0 to about 4.4 and including, as the lipid component, a lipid emulsion stable at the above pH range for prolonged periods of time. The lipid component comprises elemental lipid sources such as: medium chain triglycerides (MCT) or other structural triglycerides, a vegetable oil such as, corn oil, a suitable emulsifier, and a starch-like material in quantities sufficient to maintain a stable emulsion in the pH range of the composition. The lipid component preferably includes a modified starch and the amino acid component includes a nutritionally acceptable balance of amino acids and/or relatively low molecular weight peptides. The aqueous combination of the ingredients comprising this invention is non-browning with time and/or at elevated temperatures and can be pasteurized or sterilized without the formation of Maillard reaction-related by-products or undesirable coloration.

SPECIFIC EMBODIMENTS

The elemental dietary composition of this disclosure includes three major components: amino acids and/or peptides as a nitrogen source (herein referred to as the amino acid component), carbohydrates and lipids. The composition may also contain relatively minor amounts of vitamins and minerals. It should be pointed out that the liquid diet of this disclosure is an elemental diet in which the major components are made available in an "elemental" form which can be readily assimilated and metabolized once ingested. Elemental forms of these components are described below.

As used herein, the term amino acid source includes either or both of selected amino acids or selected peptides as described below.

Amino acids and/or peptides which can be used for the amino acids component are chosen for their solubility and ability to meet specific nutritional needs. The specific combination of amino acids useful for a given application is referred to as an amino acid profile. Examples of applications for specific amino acid profiles include, for example, specific amino acid combinations (or profiles) for short gut syndrome, kidney and liver disfunction, inborn metabolic disorders, special diets for pediatric use, and the like. In general, diets useful for adult nutrition utilize a NER/PER of 2.5 or greater. As used herein, PER refers to the Protein Efficiency Ratio which is a measure of the weight gain of a growing animal divided by protein intake [i.e. PER=weight gain(gm)/protein intake(gm)]. NER refers to Nitrogen Efficiency Ratio [i.e. NER=weight gain(gm)/nitrogen intake(gm)]. Thus, to achieve a diet having a NER/PER of 2.5 or more, one preferred amino acid profile, shown in detail below, follows or imitates the amino acid profile of lactalbumin found in milk.

When low molecular weight peptides are used as the nitrogen source, care must be taken to avoid peptides which have too high a molecular weight as this can result in precipitation, emulsion breakdown and an undesirable brownish product. For example, peptides made from hydrolyzed lactalbumin having the following molecular weight profile should not be used in the liquid elemental diet of this disclosure: