ELEMENTAL NUTRITIONAL PRODUCTS

FIELD OF THE INVENTION

This invention relates to an emulsifier system for liquid or powder nutritional products.

BACKGROUND OF INVENTION

In addition to its essential role in nutrition, protein is an important contributor to the physical properties of formulated foods including infant formulas and foods formulated for special medical purposes. Intact proteins and partially hydrolyzed proteins contribute to the emulsification of a fat component of a nutritional product due to their favorable hydrophilic-lipophilic balance that facilitates adsorption at the interface during preparation of product. Intact proteins and partially hydrolyzed proteins also contribute to forming a strong and cohesive interfacial film that minimizes droplet coalescence in the product resulting in a stable emulsion which allows manufacture of liquid and powder nutritional products with acceptable physical properties and shelf-life.

Foods containing extensively hydrolyzed protein and/or free amino acids are frequently referred to as elemental diet products. Elemental diets contain the altered protein components to fit with special medical purposes for a selected population with suspected protein allergy, protein intolerance, malabsorption disorders, or inborn errors of metabolism. Hypoallergenic infant formulas represent an important diet alternative for babies with demonstrated protein allergy to cow's milk. In contrast to intact protein or partially hydrolyzed protein, extensively hydrolyzed protein and amino acids have very poor or negligible emulsifying properties. In the products utilizing extensively hydrolyzed protein and/or free amino acids, commercially available emulsifiers have been used to achieve acceptable physical characteristics. One such emulsifier frequently used in infant formulas and other formulated nutritional products having extensively hydrolyzed or free amino acids is an octenyl succinic anhydride modified starch (hereinafter "OSA modified starch"). It is believed that the modification of the starch contributes to emulsion stability of the formulation by reducing the boundary tension between the immiscible fluids oil and water. The OSA starch is available commercially as intact (no molecular weight reduction) or dextrinized (molecular weight reduced by heat or enzymatic treatment and the like).

When proteins, hydrolyzed proteins and/or amino acids and carbohydrates are combined in an aqueous solution, these components have a tendency, especially with time and at elevated temperatures, to form a brownish solution and undesirable by-products due to the well-known Maillard reaction(s). This problem is particularly challenging for formulas prepared with extensively hydrolyzed proteins and/or free amino acids. U.S. Pat. No. 4,414,238 (Schmidl) teaches an elemental diet composition that uses an OSA modified starch in combination with a mono- and diglycerides emulsifier at a pH range of from about 3 to 4.4 to provide acceptable emulsification stability in conjunction to reduce the Maillard reaction. The pH range is attributed to providing an aqueous combination that is non-browning with time and at elevated temperatures and can be pasteurized or sterilized without the formation of Maillard reaction related by-products or undesirable browning.

U.S. Pat. No. 4,670,268 (Mahmoud) teaches that an OSA modified starch may be used in formulations with extensively hydrolyzed proteins at a higher pH of from 6 to 7. This patent also teaches that mono- and diglycerides, lecithin and polyglycerol esters of fatty acids were found to be ineffective in producing a stable hypoallergenic formula. As provided in Col. 4, lines 13–16 of U.S. Pat. No. 4,670,268, the hypoallergenic formula made with these emulsifiers yielded unstable emulsions and developed an objectionable cream layer within 24 hours of sterilization.

The OSA modified starch has been found incompatible with simple emulsifiers, as discussed in the prior art literature and exemplified in the Examples section herein. Thus, in commercially available nutritional products with extensively hydrolyzed proteins, dextrinized OSA modified starch is often used as a sole emulsifier in elemental diet compositions (see, e.g., U.S. Pat. No. 4,670,268).

While products with extensively hydrolyzed proteins and/or amino acids are commercially available, alternative emulsifying systems for elemental diets are needed.

SUMMARY OF INVENTION

An alternative emulsifying system for elemental diet compositions has been discovered. The inventive elemental diet composition comprises (a) a protein source selected from the group consisting of extensively hydrolyzed protein, free amino acids, short-chain peptides, or a mixture thereof; (b) a lipid source; (c) a carbohydrate source; and (d) an emulsifying system comprising OSA modified starch and an acetylated monoglyceride emulsifier.

The inventive composition may be prepared as a powder or liquid nutritional composition for formulas prepared for infant, pediatric and adult populations in need of an elemental diet. The inventive composition may be prepared as a nutritionally complete diet by including vitamins and minerals at acceptable levels. The invention provides a commercially acceptable product in terms of desired stability and physical characteristics and the product demonstrates little to no observable browning effect by-products associated with a Maillard reaction. Further, the inventive composition is substantially homogeneous for an acceptable period after reconstitution (or for the shelf-life if prepared as a liquid). The invention is particularly useful for hypoallergenic infant formula preparations, although it is equally applicable to other elemental diets specific to a selected population with suspected protein intolerance, malabsorption disorders, inborn errors of metabolism, and the like.

DESCRIPTION OF INVENTION

The protein source may be selected from any appropriate nitrogen sources, such as, extensively hydrolyzed protein, free amino acids, short-chain peptides and mixtures thereof appropriate for formulation of elemental diet compositions targeted for populations having specific nutritional needs. The actual amino acid/peptide content will depend upon the desired nutritional goals of the particular composition. Favored proteins include extensively hydrolyzed protein hydrolysates prepared from acid or enzyme treated animal and vegetable proteins, such as, casein hydrolysate, whey hydrolysate, casein/whey hydrolysate, soy hydrolysate, and mixtures thereof. By "extensively hydrolyzed" protein hydrolysates it is meant that the intact protein is hydrolyzed into peptide fragments whereby a majority of peptides fragments have a molecular weight of less than 1000 Daltons. More preferably, from at least about 75% (preferably at least about 95%) of the peptide fragments have a molecular weight of less than about 1000 Daltons. Free amino acids and synthetic short peptide chains may also be either substituted for or added to the protein hydrolysates as the nitrogen source so long as the nutritional composition has an