

PARTIALLY HYDROLYZED PECTIN IN NUTRITIONAL COMPOSITIONS

FIELD OF THE INVENTION

The present invention concerns partially hydrolyzed pectin of a particular molecular weight range for use in nutritional compositions.

BACKGROUND OF THE INVENTION

Diarrhea is a major problem in a substantial percentage of patients receiving enteral feeding (see, for example, Guenter, P. A., et al., "Tube-feeding-related Diarrhea in Acutely Ill Patients," *J. Parenter. Enter. Nutr.*, 15:277-280, 1991). Apart from patient discomfort, additional nursing care and hospitalization costs, such diarrhea can severely compromise patient health, because of depletion in fluid, electrolytes and other nutrients (see, for example, Frankenfield, D. C. and Beyer, P. L., "Soy-polysaccharide Fiber: Effect on Diarrhea in Tube-fed, Head-injured Patients," *Am. J. Clin. Nutr.*, 50:533-538, 1989). Therefore, control of diarrhea has major clinical, psychosocial and financial benefits. Obviously, nutritional compositions which can help control diarrhea are highly desired.

The nutritional significance of dietary fiber has become apparent in the last two decades, and more recently, dietary fiber also has been included in enteral nutrition formulas. Dietary fiber has been suggested to be beneficial in diarrhea management because it may regulate GI transit time (Potkins, et al., "Effects of Structural and Non-structural Polysaccharides in the Diet of the Growing Pig on Gastric Emptying Rate and Rate of Passage of Digesta to the Terminal Ileum and Through the Total Gastrointestinal Tract," *Br. J. Nutr.*, 65:391-413, 1991), adsorb excess luminal fluid, and/or be fermented to short chain fatty acids which stimulate colonic mucosal function and thus water and electrolyte absorption.

The effectiveness of commercially available enteral nutrition formulas with fiber (soy polysaccharide) is controversial (see, for example, Guenter, P. A., et al., "Tube-feeding-related Diarrhea in Acutely Ill patients," *J. Parenter. Enter. Nutr.*, 15:277-280, 1991; Frankenfield, D. C. and Beyer, P. L., "Soy-polysaccharide Fiber: Effect on Diarrhea in Tube-fed, Head-injured Patients," *Am. J. Clin. Nutr.*, 50:533-538, 1989; Shankardass, K., et al., "Bowel Function of Long-term Tube-fed Patients Consuming Formula With and Without Dietary Fiber," *J. Parenter. Enter. Nutr.*, 14:508-512, 1990). A more successful approach may be the inclusion of highly fermentable soluble fiber, such as pectin or guar gum (Zimmaro, D. M. et al., "Isotonic Tube Feeding Formula Induces Liquid Stool in Normal Subjects: Reversal by Pectin," *J. Parenter. Ent. Nutr.*, 13:117-123, 1989).

Pectin or guar gum as such are not suitable for use in liquid nutrition formulas as a source of dietary fiber, because they form very viscous aqueous solutions even at low concentrations. However, hydrolysis of pectin or guar gum dramatically decreases their viscosity (see, for example, vollmert, B., "Uber den alkalischen Pektinabbau," *Makromol. Chemie*, 5:110-127, 1950; Albersheim, P., et al., "Splitting of Pectin Chain Molecules in Neutral Solutions," *Arch. Biochem. Biophys.*, 90:46-51, 1960; T. P. Krovtschenko, I. Arnold, A. G. J. Vorogen and W. Pilnik, "Improvement of the Selective Depolymerization of Pectic Substances by Chemical β -elimination in Aqueous Solution," *Carbohydr. Polym.*, 19:237-242, 1992). Little is known, however, about

the use of such hydrolyzed fiber in nutritional products.

It would be highly desirable to have a nutritional product containing a soluble fiber which is of sufficiently low viscosity to be suitable for use in nutritional products and be useful for the management of diarrhea.

SUMMARY OF THE INVENTION

The present invention is based on the discovery that pectin of limited hydrolysis is effective in the management of diarrhea. This observation is unexpected in that other partially hydrolyzed soluble fibers, such as guar gum, are not effective. We have also found that the extent of hydrolysis is critical in that extensively hydrolyzed (i.e., to a peak molecular weight level of 3,300 or lower) pectin loses its ability to control diarrhea. We have also found that in some instances a mixture of partially hydrolyzed pectin with an insoluble or non-fermentable fiber can be used.

Therefore, the present invention is directed to a nutritionally complete composition comprising (a) a nitrogen source, (b) a non-fiber carbohydrate source, (c) a lipid source, (d) vitamins and minerals, and (e) a fiber system comprising partially hydrolyzed pectin having a peak molecular weight less than unmodified pectin and greater than 3,300. This composition will be referred to herein as the "nutritionally complete" composition.

In another embodiment the present invention is directed to a nutritional composition which is not necessarily nutritionally complete. Such a composition can be a nutritional supplement and can be described as a nutritional supplement composition comprising (1) a fiber system comprising partially hydrolyzed pectin having a peak molecular weight less than unmodified pectin and greater than 3,300, and (2) 100% of the RDI of vitamins and minerals per 500 to 3000 kcal of total composition. This composition will be referred to herein as the "nutritional supplement".

When the term "composition" is used herein without modifier, such term shall apply to either the nutritionally complete composition or the nutritional supplement.

In another aspect, the present invention is directed to a fiber system comprising (i) partially hydrolyzed pectin having a peak molecular weight less than unmodified pectin and greater than 3,300; and (ii) at least one insoluble fiber.

In still another aspect, the present invention is directed to a fiber system comprising (I) partially hydrolyzed pectin having a peak molecular weight less than unmodified pectin and greater than 3,300; and (II) at least one non-fermentable fiber.

The present invention also concerns a method for treating diarrhea in a patient using the fiber of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1—Fecal output per gram of food intake for Example 6. Means \pm standard deviations. Means with common letters are not statistically significantly different (ANOVA, Scheffe's F-test, $p \leq 0.05$).

FIG. 2—Fecal dry matter output per gram of food intake for Example 6. Means \pm standard deviations. Means with common letters are not statistically significantly different (ANOVA, Scheffe's F-test, $p \leq 0.05$).

FIG. 3—Fecal moisture for Example 6. Means \pm standard deviations. Means with common letters are not statistically significantly different (ANOVA, Scheffe's F-test, $P \leq 0.05$).

FIG. 4—Fecal dry matter output for Example 7. Means \pm standard deviations. Means with common letters are