

LIQUID NUTRITIONAL PRODUCT

There is provided in accordance with the present invention a fiber-containing, isotonic, nutritionally complete liquid food for total enteral support. Examples of individuals who may require tube feeding are critically ill, chronically disabled, frail, elderly and comatose patients who are unable to chew food, and patients suffering from a diseased or traumatized esophagus who are unable to swallow food.

An objective of the present invention is to provide a liquid nutritional product having a fat level with a fatty acid profile which meets the recommendations contained in *RECOMMENDED DIETARY ALLOWANCES*, 10th *EDITION* Food and Nutrition Board of the National Research Council, National Academy of Sciences, 1989 for no more than 30% of total calories as fat, less than 10% of calories from saturated fatty acids, no more than 10% from polyunsaturated fatty acids, and a ratio of n-6 to n-3 fatty acids in the range of 2 to 10, most preferably 4 to 10.

Another objective of the present invention is to provide a liquid nutritional product containing both soluble and insoluble, and both fermentable and nonfermentable dietary fiber at a level of about 4 to 5 grams per 8 fluid ounce serving. This level of dietary fiber will meet the recommendations of the U.S. Food and Drug Administration, the U.S. Department of Health and Human

invention to meet the above limitations, and some of which do not meet these limitations. The values in Table I unless otherwise noted were calculated using a highly sophisticated computer program having a very high degree of accuracy when verified by actual laboratory analysis. In each instance the fat source as a whole comprises by weight about 3.9% soy lecithin, and the formulation of the remaining 96.1% of the fat source is varied as set forth below. In TABLE I: Blend A is 50% MCT/40% canola oil/10% soy oil which is the same blend as in a commercially available nutritional product for tube feeding having the trade name JEVITY® and is available from the Ross Laboratories Division of Abbott Laboratories (actual laboratory analysis); Blend B is 50% MCT/50% soy oil which is the same blend as in a commercially available nutritional product for tube feeding having the trade name ULTRACAL® and is available from Mead-Johnson (taken from product handbook); Blend C is 50% MCT/50% canola oil which is the same blend as in a commercially available nutritional product for tube feeding having the trade name ISOSOURCE® and is available from Sandoz Nutrition Corp.; Blend D is 100% corn oil; Blend E is 100% canola oil; Blend F is 32.9% soy oil/67.1% high oleic safflower oil; Blend G is 95% high oleic safflower oil/5% linseed oil; and Blend H which is the blend used in the best mode of the invention contemplated at the time of filing a patent application is 50% high oleic safflower oil/30% canola oil/20% MCT.

TABLE I

	Desired	BLEND							
		A	B	C	D	E	F	G	H
Total Calories From Saturated Fatty Acids	<10%	14.7%	18.0%	~15%	4.17%	2.08%	3.03%	2.47%	7.69%
Total Calories From Polyunsaturated Fatty Acids	≤10%	10.32%	12.5%	4.9%	17.88%	9.25%	9.95%	6.38%	5.69%
n-6:n-3 ratio	2-10	37.2	5.92	2.62	56.81	2.51	9.93	5.67	5.51

Services, and the American Dietetic Association for a minimum daily intake for fiber of 20 to 35 grams per day, if a person is fed five 8 fluid ounce servings of the new product per day.

Another objective of the present invention is to provide a liquid nutritional product which will provide at least 100% of the U.S. Recommended Daily Allowance for vitamins and minerals in a nutrient base of 1,250 calories. This will permit patients with reduced energy requirements to be provided with necessary vitamins and minerals.

In order for a liquid nutritional product according to the invention to meet the limitations that no more than 30% of the total calories are fat, less than 10% of the calories are from saturated fatty acids, no more than 10% of the calories are from polyunsaturated fatty acids, and the ratio of n-6 to n-3 fatty acids is in the range of 2 to 10, preferably 4 to 10, at least one of the fat sources must be a source of alpha-linoleic acid, such as canola oil, soy oil or linseed oil. Preferably, the fat source further comprises a source of oleic acid, preferably a source which comprises over 70% oleic acid such as high oleic safflower oil or high oleic sunflower oil. Most preferably the fat source further comprises medium chain triglycerides (MCT). The following TABLE I contains examples of fat sources, some of which allow a nutritional product according to the

Numerous types of dietary fibers are currently available. Basically, dietary fiber passes through the small intestine undigested by enzymes and is a kind of natural and necessary laxative. Dietary fiber is understood to be all of the components of a food that are not broken down by enzymes in the human digestive tract to produce small molecular compounds which are then absorbed into the bloodstream. These components are mostly celluloses, hemicelluloses, pectin, gums, mucilages, lignin and lignin material varying in different plants according to type and age. These fibers differ significantly in their chemical composition and physical structure and subsequently their physiological function. Those skilled in the art have attempted to identify fibers (or fiber systems) which will normalize bowel function, alter glucose absorption, lower serum cholesterol and/or serve as an indirect energy source for the colon.

There are many publications relating to dietary fiber. Japanese published patent application Kokai No. Hei 2-227046 published Sept. 10, 1990 teaches the use of dietary fiber, including gum arabic, as emulsifying agents in food products.

U.S. Pat. Nos. 4,565,702 and 4,619,831 teach dietary fiber compositions prepared by coating an insoluble fiber with a soluble fiber.