

INFANT FORMULA CONTAINING A SOY POLYSACCHARIDE FIBER SOURCE

TECHNICAL FIELD

The present invention relates generally to a liquid nutritional product, and more particularly, to an infant formula for use in the management of infantile colic.

BACKGROUND ART

Colic is one of the most confusing subjects facing pediatrics today. In the absence of a standard definition of "colic" it is difficult to compare one study on "colicky infants" with another. Furthermore, given the absence of a standard definition, studies assessing the causes and/or management of colic undoubtedly involve a heterogeneous group of infants with both a variety of problems as well as no problem at all.

Numerous reports in the pediatric literature suggests that colic occurs in at least 10% to as high as 30% of both breast-fed and formula-fed infants. Colic is often described as unexpected paroxysms of crying or fussing which generally occur in the evening hours. These episodes begin in the first weeks of life and often subside by the time the infant reaches 3-4 months of age. In normal infants, crying and fussing behavior peaks at 2.75 hours per day at 6 weeks of age. Colicky infants are often defined as those infants who cry and fuss for more than 3 hours per day at 6 weeks of age, although it must be recognized that this is not a uniform definition. Even when colic has been defined, many studies have not documented it in their own study subjects prior to attempts at treatment.

A significant amount of literature on colic is directed toward the discovery of an organic or physical cause of the presumed pain. Examples of suggested causes include the assumption that the infant is suffering gastrointestinal pain from the maldigestion of carbohydrate, abnormal gastrointestinal motility, immaturity of the gastrointestinal tract or the central nervous system, allergy to cow-milk protein, or gastroesophageal reflux. Alternatively, an equal body of literature proposes a non-organic etiology for colic, such as the intrinsic temperament of the infant coupled with maternal/caretaker maladaptation or psychological problems.

Currently several relatively diverse therapies are employed in attempts to treat colic. To some, the most effective treatment of colic is parental counseling whereby the parental reaction to a child's crying is modified in the belief that this parental reaction actually aggravates the situation. To those who believe that colic is somehow related to a food allergy to intact protein, certain formulas incorporate hydrolysates, wherein the protein in the formula is broken down to reduce the allergenic response. However, this specific method of treatment is both very expensive and questionable as to its effectiveness. To those who believe that colic is related to an immature nervous system being overloaded, another current therapy often employs sedative or anti-spasmodic drugs. Still another therapy used in the treatment of colicky infants involves the use of mechanical rocking or vibrating devices. Unfortunately, each of these treatments is often ineffective and hence can increase parental anxiety. Increased anxiety has led to reports in the literature of parental abuse of the colicky infant. Regardless of the treatment, an infant who suffers from colic typically cries and

fusses for more than 3 hours each day over an approximate 3 to 4-month period of time.

Fiber is a normal dietary constituent once solid foods become part of the diet and the child is no longer exclusively milk-fed, generally after 4 to 6 months of age. Typically fiber is introduced into the infant's diet only after the infant is consuming solid foods such as cereals, fruits and vegetables which contain fiber. As such, dietary fiber would not normally be a constituent of the diet of infants who experience colic.

Prior to the present invention, fiber has not been intentionally incorporated into infant formula for the specific treatment of colicky infants. In fact, no dietary treatment has been conclusively documented in controlled double-blinded studies as alleviating infantile colic. Increased fiber has been added to the diets of older infants, i.e. those older than 6 months of age, and toddlers for the treatment of diarrhea and constipation. In addition, dietary fiber has been successfully used in adults to treat numerous conditions.

It is thus apparent that the need exists for an improved infant formula that will significantly decrease the symptoms of colic in a significant number of infants.

DISCLOSURE OF THE INVENTION

There is disclosed an infant formula, said formula comprising: 1) protein, said protein being of a concentration of between 10 and 25 grams per liter of formula; 2) fat, said fat being of a concentration of between 20 and 45 grams per liter of formula; 3) carbohydrates, said carbohydrates including those from total dietary fiber being of a concentration of between 60 and 110 grams per liter of formula; and 4) total dietary fiber, said fiber being of a concentration of between 3.1 and 14.1 grams per liter of formula.

As used herein, total dietary fiber content is determined by the AOAC method as set forth in Prosky, L, Asp, N-G, Schweizer, TF, DeVries, JW and Furda, I, "Determination of Insoluble, Soluble, and Total Dietary Fiber in Foods and Food Products: Interlaboratory Study", *J. Assoc. Off. Anal. Chem.*, 1988.

The fiber source utilized in this invention is soy polysaccharide derived from soy beans, also known as soya beans.

Preferably the protein has as its source soy protein isolate, or sodium and calcium caseinates or a blend thereof; said fat has as its source soy, coconut or corn oil or another vegetable oil or a blend thereof; and said carbohydrates other than total dietary fiber have as their source sucrose, corn syrup, glucose polymers, other carbohydrates or a blend thereof.

Preferably, the protein is of a concentration of between 15 and 21 grams per liter of formula, said fat is of a concentration of between 23 and 40 grams per liter of formula, and said carbohydrates including total dietary fiber are of a concentration of between 70 and 110 grams per liter of formula. More preferably, said protein is of a concentration of between 15 and 20 grams per liter of formula, said fat is of a concentration of between 24 and 38 grams per liter of formula, said carbohydrates including total dietary fiber are of a concentration of between 75 and 110 grams per liter of formula, and said total dietary fiber is of a concentration of between 3.5 and 14.0 grams per liter of formula.

In a preferred embodiment of the invention, said protein is of a concentration of approximately 19.6 grams per liter of formula and has as its source soy protein isolate, said fat is of a concentration of approxi-