

## HYPALLERGENIC MILK PRODUCTS FROM NATURAL AND/OR SYNTHETIC COMPONENTS AND PROCESS OF MAKING

### CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of my copending, commonly assigned U.S. patent application Ser. No. 562,777, now U.S. Pat. No. 5,064,674, filed Aug. 3, 1990, which is a continuation-in-part of U.S. patent application Ser. No. 297,451, filed Jan. 13, 1989, now U.S. Pat. No. 4,954,361. The entire disclosures of U.S. Pat. No. 5,064,674 and U.S. Pat. No. 4,954,361 are incorporated herein by reference.

### FIELD OF THE INVENTION

A hypoallergenic milk made from the synthetic equivalent of milk mineral salts is disclosed herein. The hypoallergenic milk has the flavor and smell of whole natural milk, but lacks the component which causes allergic reactions. The hypoallergenic milk has the favorable features of cow's milk, but lacks foreign animal protein, and therefore may thus be regarded as "humanized" cow's milk.

### BACKGROUND OF THE INVENTION

Many persons suffer from various allergies, many of which are caused by ingesting food containing allergens. Although the biochemistry of allergic reactions is not precisely understood, it is believed that the allergens cause, upon ingestion or other contact with the body, a specific reagin (or skin sensitizing antibody) to be formed in the bloodstream. The ability to produce reagins, chemically identified as IgE, in response to a given allergen is thought to be an inherited characteristic that differentiates an allergic person from a non-allergic person. The specificity of the allergen-reagin reaction and its dependence on molecular configuration of the allergen and reagin is similar to the antigen-antibody reaction. The degree of sensitization is dependent upon the extent of exposure to or ingestion of the allergen. In this respect, the allergen molecule, which is often a protein, may be regarded as a "key" which exactly fits the corresponding structural shape of the reagin molecule which may be likened to a "lock". When the key is inserted into the lock, an allergic reaction results.

Different materials contain different allergens. Not all persons may have the reagin with which a particular allergen can react. Therefore, some persons are not allergic to particular materials. However, when a particular reagin reacts with a specific allergen, an allergic reaction results in any number or type of symptoms. Allergic reactions range from very mild symptoms to death. For example, symptoms, both mild and severe, include skin rashes (allergic eczema and urticaria), dermal symptoms, respiratory symptoms (including allergic rhinitis and bronchial asthma), gastrointestinal symptoms, and migraine. Violent illnesses have been known to include shock-like reactions, vascular collapse and allergic anaphylaxis.

Many allergists have recognized that milk contains proteins which are allergens. The allergens of cow's milk frequently cause the formation of reagins (IgE) in many persons. Thus, many persons, including both adults and children, are allergic to cow's milk.

Milk is very frequently used in popular food products. It is used not only in cooking and baking, but it is

included in hidden ways as well. For example, casein, caseinate milk solids, whey, whey solids, and lactalbumin are milk products which are components of cookies, cheeses, chocolate (in the form of milk chocolate), ice cream, butter and may be used as flavoring for other food products, such as breakfast cereals, hot and cold beverages, and desserts. These products can also be found in gravies, breadings, whole, dry or evaporated milk, yogurt, sherbet, breads, waffles, creamed vegetables, mashed potatoes, pudding, creamer or any diverse products such as hot dogs or spaghetti.

Milk products, which are marketed today as hypoallergenic milk, are neither uniformly hypoallergenic to all patients, nor made from cow's milk. For example, heat processed milk, in which albumin is denatured, is of modest benefit to only a limited number of patients. A hypoallergenic vegetable soybean milk formulation devised in China has an objectionable smell and after taste. Hypoallergenic milk produced by the acid process which imitates the stomach's digestive process by utilizing hydrochloric acid to break up proteins, e.g. casein, has an objectionable smell and taste.

Accordingly, there is a need for a hypoallergenic milk which also has the taste and smell of cow's milk.

U.S. Pat. No. 4,293,571 discloses a process for the purification of purified protein hydrolysate. In this process, an aqueous solution of protein is subjected to hydrolysis, then is heat treated to denature the protein. The heat-treated material is then ultrafiltered to eliminate protein.

U.S. Pat. No. 4,402,938 discloses a food and method for making the same from colostrum and milk. In this process, the udder of an ungulate is stimulated with an antigen-like material so that the food factor of the whey is enhanced. The enhanced milk is subsequently ultrafiltered. The retentate is discarded and the permeate is saved. Preservatives are added to the milk/colostrum prior to ultrafiltration.

The inventor's commonly assigned U.S. Pat. No. 4,954,361 and application Ser. No. 562,777, filed Aug. 3, 1990 disclose hypoallergenic milk products from ultrafiltration of cow's milk. The resulting good-fasting products are substantially free of cow's milk protein and fat. While these products represent an advance in the state of the art, they are derived from whole milk or fractions thereof. What is needed is a product which has the good taste and nutritional value of milk-based products, but which may be prepared from synthetic sources. According to the invention hereinafter described, the mineral salts, carbohydrate and protein do not necessarily have to be derived from milk.

### SUMMARY OF THE INVENTION

A hypoallergenic milk product is provided comprising (i) a mineral salt component comprising a mixture of mineral salts approximating the mineral content of natural milk, (ii) a carbohydrate component comprising one or more carbohydrates and (iii) a hypoallergenic protein component which may advantageously comprise hypoallergenic protein per se, amino acids, polypeptides having a molecular weight of not more than about 5.0 kDa, or a combination thereof.

The hypoallergenic milk product is prepared by the steps of forming an aqueous mixture of the mineral salt component, carbohydrates, and hypoallergenic protein component. One or more of the separate components, and/or any combination thereof, are filtered through a