

NUTRITIONAL FORMULA

This invention relates to a hypoallergenic (oligoantigenic) nutritional formula such as may be used for infants and other with allergies and/or digestive problems and/or malnutrition and/or hyperactivity; and/or migraine.

The incidence of food allergy in the paediatric population may be as high as 38%, according to some studies. The incidence of allergy is highest in infancy and childhood and decreases with age. Cow's milk is the most common allergen, affecting approximately 7% of the general paediatric population and possibly up to 30% of allergic children. Generally, when a patient presents with an allergy to cow's milk, a soya-based formula is prescribed. Yet soya allergy occurs in approximately 10-30% of children who are allergic to cow's milk. There is also an allergic cross-reaction between goat's milk and cow's milk. Goat's milk is not usually recommended, for children under the age of six months.

BACKGROUND OF THE INVENTION

Special hypoallergenic formulas are commercially available based on hydrolyzed protein, but they can be expensive and unpalatable—infants may refuse them.

One example of such formulas is to be found in U.S. Pat. No. 4,670,268, which explains that protein hydrolysates, comprising short peptide fragments and/or free amino acids have been found to be less immunogenic or allergenic than intact proteins. The immunogenicity of the formula depends, it is stated, largely on the extent of hydrolysis of the selected protein hydrolysate, and the patent recommends that the protein hydrolysate should be extensively hydrolyzed to yield very short peptides and free amino acids.

As noted in U.S. Pat. No. 4,670,268, however, the extensively digested and hypoinmunogenic protein hydrolysates have the undesirable characteristic of loss of capacity to emulsify fat and form physically stable emulsions that do not separate during storage. As stated in U.S. Pat. No. 4,670,268, another common problem encountered in the preparation of hypoallergenic formulas is the formation of undesirable brown colour as a result of the reaction between the carbonyl groups of reducing sugars and the nitrogen-amine containing compounds such as amino acids in the formula (Maillard type reaction) especially at elevated temperatures encountered during sterilization.

In common with U.S. Pat. No. 4,414,238, which is referred to in U.S. Pat. No. 4,670,268, the use of a low dextrose equivalent hydrolyzed starch is particularly recommended to minimise Maillard type reactions and brown colour formation, and the inclusion of octenyl succinic anhydride modified starch is prescribed in order to form a stable emulsion.

U.S. Pat. No. 4,670,268 recommends further supplementation of the hydrolyzed protein source with various free amino acids to provide a nutritionally balanced amino acid content.

The formulas of both U.S. Pat. Nos. 4,670,268 and 4,414,238 are primarily intended to be supplied in ready-to-use liquid form, although U.S. Pat. No. 4,670,268 mentions the possibility of concentration and of supplying in powder form for reconstitution by adding water prior to feeding.

While doubts have been raised about the use of octenyl succinic anhydride, probably the main problems with hydrolysed hypoallergenic formulas are that they could be expensive, and not always very palatable.

SUMMARY OF THE INVENTION

The present invention provides a novel hypoallergenic (oligoantigenic) nutritional formula which does not have the aforementioned disadvantages.

The invention provides a hypoallergenic/(oligoantigenic) nutritional formula in a form which resembles milk in appearance and stability, or which can be made to resemble milk through a process of realimentation such as for example the addition of a liquid such as water.

The invention provides an hypoallergenic (oligoantigenic) nutritional formula comprising a homogeneous powder of such fineness that it will form a water suspension resembling milk which will have acceptable stability, will keep fresh in a refrigerator after allementation for approximately 24 hours and will not block a standard feeding teat. The formula comprises muscle protein and/or meat selected for its low allergenicity as the sole or substantially the sole protein content together with lipid and carbohydrate additives, and a vitamin and mineral content, all in such proportions as will constitute a nutritionally balanced food.

By selecting the muscle protein and/or meat for its low allergenicity, hydrolysis probably becomes unnecessary, and in the best mode of the invention to be more particularly described hereinafter, the protein is not hydrolysed at all, though the possibility of using hydrolyzed muscle protein and/or meat is not excluded.

The protein may be derived from the muscle protein and/or meat of domesticated animals such as pork, beef/veal, mutton/lamb; from poultry, e.g. turkey, chicken, duck and from other birds e.g. pigeon; and possibly from fish, marsupials e.g. kangaroo etc; and even reptiles e.g. crocodile etc. Whilst something is known of the allergenicity of the common types of meat and fish it would be necessary to carry out trials in order to establish the allergenicity of the more exotic protein sources before they are used.

At this juncture it should be noted that some patients exhibit food intolerance—for present purposes, this and allergy may be considered equivalent conditions, inasmuch as they most probably are connected with the same or similar foods. The formula of the present invention is equally efficacious for either condition.

It should also be noted that it can by no means be claimed that allergies and food intolerance are perfectly understood, and it may well be the case that the incidence of intolerance and allergic reaction to a particular foodstuff will be different in different groups of people.

What appears to be generally true, however, is that pure muscle protein and/or meat (i.e. no skin, fat, bone or offal inclusions) has a lower allergenicity than dairy or soya products, and some muscle, particularly turkey breast meat, gives rise to a very low incidence indeed of allergic reaction and intolerance.

Whilst turkey breast meat, on that account, and on account of the fact that it is (or could be arranged to be) plentiful and inexpensive, would be the preferred choice in many countries, in other countries the choice might be different.

Since there is a reasonable choice of convenient muscle protein and/or meat sources of low allergenicity that would be feasible on economic grounds, it would