

ENTERAL NUTRITIONAL WITH PROTEIN SYSTEM CONTAINING SOY PROTEIN HYDROLYSATE AND INTACT PROTEIN

The present invention relates generally to liquid nutritional products for enteral consumption and more specifically to such nutritional products which contain a partially hydrolyzed vegetable protein and intact vegetable protein.

It is believed to be medically advantageous to provide an enteral liquid nutritional product having a source of protein comprising a soy protein hydrolysate of the type manufactured using a process taught in U.S. Pat. No. 4,100,024, which is incorporated herein for the purpose of teaching a process for manufacturing a soy protein hydrolysate for use in the practice of the present invention. Briefly, this process for the preparation of polypeptides from soy protein soluble in an aqueous media at pH's in the range of 2 to 7 involves: hydrolyzing soy protein with a microbial, alkaline proteinase in a concentration ranging from 4 to 25 Anson units per kg of soy protein at a substrate concentration of between 5 and 20% w/w soy protein, at a pH in the range of from 7.5 to 8.5, until a degree of hydrolysis in the range of from about 8 to 15% is attained, whereafter the enzyme is inactivated by reduction of pH with a food grade acid, then recovering the supernatant from the precipitate. However, it is understood that a soy protein hydrolysate produced by any other process which has the characteristics elaborated upon herein may be used in the practice of the present invention.

An example of a nutritional product containing such a soy protein hydrolysate is taught in U.S. Pat. No. 4,959,350, but this prior art nutritional product has a pH of lower than 4.5 (as compared to a pH of 6.4 to 6.6 in the product of the present invention).

The nutritional product of the present invention has been manufactured using soy protein hydrolysate (SPH) obtained from NOVO Industri A/S, Bagsvaerd, Denmark, (NOVO) manufactured according to the above described process. The properties of a soy protein hydrolysate which is suitable for use in the practice of the present invention have been determined by actual analysis of samples from several lots of soy protein hydrolysate obtained from NOVO Industri and/or specifications selected in accordance with desired properties.

Per the manufacturer's specifications SPH obtained from NOVO comprises by weight, not less than 76%, preferably not less than 80% protein, not more than 1% fat, and not more than 5.5%, preferably not more than 4.8% ash. A 5% slurry (by weight) of the soy protein hydrolysate in water has a pH in the range of about 4.2 to 4.3, but in any instance less than 4.5. The degree of hydrolysis (DH) of the soy protein hydrolysate (AN/TN \times 100) is in the range of about 14 to 17 and most preferably about 16.

The amino acid profile of the soy protein hydrolysate that has been used in the practice of the present invention is presented in Table 1, and the mineral profile is presented in Table 2. The molecular weight profile is presented in Table 3 for soy protein hydrolysate (SPH) having about a degree of hydrolysis of 16 with the approximate molecular weight partition determined by size exclusion chromatography of samples from 4 lots of SPH. The molecular weight profile of the soy protein hydrolysate is believed to be very important because the particles sizes are related to their physical activity and product functionality. That is to say, for the SPH used in the practice product of the present invention the

molecular weight profile indicates a large peptide content (molecular weights of 1500-5000) and a small free amino acid content (less than 1 g of free amino acids per 100 g SPH). The mineral profile of the soy protein hydrolysate is believed to be very important because it supplies most of the trace and ultratrace minerals in the nutritional product.

TABLE 1

| AMINO ACID PROFILE OF SOY PROTEIN HYDROLYSATE (g/100 g) | |
|--|-----------|
| Aspartic acid | 9.8-10.4 |
| Threonine | 2.9-3.2 |
| Serine | 3.7-4.4 |
| Glutamic Acid | 17.0-18.1 |
| Proline | 4.4-4.9 |
| Glycine | 3.2-3.3 |
| Alanine | 3.0-3.2 |
| Valine | 2.9-3.6 |
| Methionine | 0.9-1.1 |
| Isoleucine | 3.0-3.7 |
| Leucine | 5.1-5.3 |
| Tyrosine | 2.7-2.9 |
| Phenylalanine | 3.3-3.5 |
| Histidine | 2.0-2.2 |
| Lysine | 5.5-5.8 |
| Arginine | 6.3-6.7 |
| Tryptophan | 0.3-0.7 |
| Cystine | 1.3-1.4 |
| Free Amino Acids | 0.4-0.7 |

TABLE 2

| | MINERAL PROFILE OF SOY PROTEIN HYDROLYSATE | |
|----------------------|---|-------------------------|
| | Preferred Range | Most Preferred Range |
| Calcium, mg/100 g | 170-350 | 170-260 |
| Sodium, mg/100 g | 370-650 | 370-520 |
| Potassium, mg/100 g | 180-600 | 180-470 |
| Magnesium, mg/100 g | 270-550 | 270-400 |
| Phosphorus, mg/100 g | 900-1500 | 900-1200 |
| Chloride, mg/100 g | 1400-2500 | 1400-2250 |
| Iron, mg/100 g | 13-25 | 13-20 |
| Zinc, mg/100 g | 3-6 | 3-6 |
| Manganese, mg/100 g | 4-8 | 5-7 |
| Copper, mg/100 g | 0.5-1.5 | 0.5-1.0 |
| Vanadium, ppm | trace-15 | 8-12 |
| Selenium, ppb | trace-350 | 150-300 |
| Chromium, ppm | trace-2.9 | 1.5-2.3 |
| Molybdenum, ppm | trace-3.7 | 2-3 |

TABLE 3

| Molecular Wt. (in Daltons) | % of Particles With This Molecular Wt. | | |
|-------------------------------|--|-------------------|-------------|
| | Average | Std. Deviation | Range |
| >5000 | 3.3 | 1.96 | 1.70-5.96 |
| 2000-5000 | 25.8 | 5.42 | 19.50-30.75 |
| 1500-2000 | 20.5 | 7.41 | 13.10-27.50 |
| 1200-1500 | 12.5 | 0.92 | 11.80-13.80 |
| 1000-1200 | 8.2 | 0.83 | 7.30-9.00 |
| 500-1000 | 19.5 | 3.02 | 16.80-23.80 |