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(57) Abstract

Modified psyllium having decreased gel hardness is prepared by exposing raw psyllium to an agent that modifies non-starch polysaccharides of psyllium for a sufficient period of time such that the recovered product has a gel hardness less than that of the starting raw psyllium or does not form a gel at all. Compositions containing the modified psyllium are also described.

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ACID AND SOLVENT MODIFICATION OF PSYLLIUM

BACKGROUND OF THE INVENTION

The present invention relates to methods for modifying psyllium to improve and extend the functionality of the psyllium. The resultant modified psyllium has improved manufacturing qualities that is prepared from raw psyllium. More particularly, the modified psyllium of the present invention has, e.g. decreased gel hardness compared to that of the raw psyllium starting material, and in preferred embodiments a 5% w/v suspension of modified psyllium in water does not gel at all or gels to an insubstantial degree.

The present invention also relates to food products containing the modified psyllium, methods for preparing the food products, and methods for treating a patient by administering the modified psyllium of the invention to the patient, e.g. to lower serum cholesterol or to provide a bulk laxative effect.

Psyllium is a mucilaginous material derived from seeds from the plants of the *Plantago* genus, which grows in certain sub-tropical regions. *Plantago ovata* is a preferred species and is commercially grown in India. The seeds of *Plantago sp.* are dark brown, smooth, boat shaped and shiny. Psyllium seed is used in whole, ground or dehusked form to make a variety of psyllium containing products.

Psyllium is an excellent source of both soluble and insoluble fibers, and has a proven cholesterol-lowering effect. There are two main types of known dietary fibers broadly classified as soluble fibers and insoluble fibers. Psyllium and certain other grains, particularly oats, contain both soluble and insoluble fibers, and are commercially available in various foods and pharmaceuticals.

Psyllium has a soluble fiber content approximately eight times greater than that of the soluble fiber content of oat bran, and thus there is great interest in psyllium for its beneficial health effects. These beneficial health effects include reducing serum total cholesterol, reducing low density lipoprotein cholesterol, lowering glycemic index and lipid levels, affecting fecal and colonic microbial metabolism, and for treatment of intestinal disorders.

Psyllium contains both neutral and acidic polysaccharides. Psyllium from different *Plantago* species vary in monosaccharide composition and content. These monosaccharides include D-xylose, D-arabinose, D-rhamnose, D-galactose, D-galacturonic acid,

4-O-methyl-D-glucuronic acid, and 2-O-(2-D-galactopyranosyluronic acid)-L-rhamnose (1,2,3,4,5). Kennedy et al. have reported detailed structural data for *Plantago ovata*. See, e.g., Kennedy et al., *Structural data for the carbohydrate of ispaghala husk ex plantago ovata forsk*, Carbohydrate Research 75:265-274 (1979). Kennedy et al. and all references cited herein are hereby incorporated by reference in their entireties. Methylation analysis and partial acidic hydrolysis have shown that the mucilage polysaccharide is a highly branched acidic arabinoxylan. The xylan backbone has both (1→4) and (1→3) linkages. Substituent groups, including rabinose, xylose, and 2-O- (galactopyranosyluronic acid)-rhamnose, are attached to the arabinoxylan chain by (1→2) and (1→3) linkages.

Psyllium husk can absorb as much as 90 times its weight in water and forms a viscous gel upon hydration. These properties are problematic to the preparation of psyllium-containing products. The mucilaginous nature of psyllium leads to an undesirable slimy or adhesive texture and mouthfeel upon hydration. This slimy mouthfeel is unpalatable and various attempts have been made to mask these undesirable characteristics.

The aforementioned difficulties become particularly troublesome when formulating beverages or drink mixes. Leis, Jr. and others have attempted to overcome some of the problems associated with a bulk laxative powdered drink mix preparation by using a raw psyllium having a specific particle size range as disclosed in U.S. Patent Nos. 5,445,831 and 5,149,541.

It is known that several variables can be controlled to inhibit psyllium hydration. These variables include formation of nuggets by extrusion as described in U.S. Patent No. 5,227,248. Changes in pH or particle size, competition of other food ingredients for water (e.g. sugar), have previously been used to improve the handling properties of psyllium.

Barbera et al. describe the inclusion of an amount of an edible acid, e.g. citric acid, high enough to slow the gellation rate but below a level that the edible acid is a flavorant to prevent agglomeration of psyllium of a particular particle size range, e.g. as described in U.S. Patent Nos. 5,234,687, 5,219,570 and 5,425,945.

U.S. Patent No.4,551,331 and its U.S. Reissue No. 32,811 describe a modified dry dietary fiber product, wherein a dietary fiber such as psyllium is coated with from 0.5 to 20% by weight of a food grade emulsifier. U.S. Patent Nos. 4,459,280 and 4,548,806 to Colliopoulos et al. also attempt to alleviate agglomeration caused by psyllium gelation by coating psyllium with a

hydrolyzed starch oligosaccharide such as maltodextrin, which may also function as an emulsifying agent.

Additionally, the USFDA requires a considerable amount of psyllium must be included in a food before a health claim can be made for reducing serum cholesterol, i.e. the amount of psyllium to be included is generally about 10g/day, which amount provides approximately 7 grams of insoluble fiber/day. However, a suitable drink mix containing such an amount of psyllium is not commercially available and cannot be formulated using raw psyllium.

It known that pH can alter the functionality of a polysaccharide by influencing the molecular changes. Changes in the pH subsequently influence the interactions between solutes and may lead to an alteration of psyllium functionality. It has been shown that the rate of psyllium hydration in a psyllium-containing suspension can be reduced by adjusting the pH of the suspension and the influence of particle size on the polysaccharide hydration has also been established. Similar to most polysaccharides, psyllium with a smaller particle has a greater hydration rate. The competition of other ingredients, such as salt and sugar, have been observed to reduce psyllium polysaccharide hydration, including the polysaccharides found in psyllium.

The desirable therapeutic effects provided by psyllium have led to many prior art psyllium- containing formulations despite the processing difficulties and alternative sources of fiber that present fewer processing difficulties. For example, various psyllium containing foodstuffs have been proposed which purport to take advantage of the natural digestion regulation properties of psyllium, or the satiating effect of psyllium, e.g. as described in U.S. Patent Nos. 3,574,634 and 4,348,379. U.S. Patent No. 5,266,473 describes the enzymatic treatment of psyllium with certain proteases to alleviate problems associated with psyllium allergenicity.

There is a need in the art to overcome the manufacturing and handling difficulties associated with psyllium to take advantage of its beneficial effects.

SUMMARY OF THE INVENTION

The present invention provides a method of modifying psyllium by treating raw psyllium to an agent that modifies the non-starch polysaccharides of the raw psyllium, e.g. to a solvent such as ethanol or to an acid, for a sufficient period of time such that the resultant modified psyllium exhibits modified physical and/or chemical properties compared to the raw psyllium

starting material, e.g. decreased gel hardness. The time period may range from about 1 hour to seven days or even greater, depending upon, e.g., processing conditions and the physico-chemical properties to be exhibited by the modified psyllium, the ratio of ingredients, and other factors that will be apparent to the skilled artisan.

In an aspect of the invention there is provided modified psyllium having a gel hardness of from 0 g to 75 g, wherein said gel hardness is measured after exposing a suspension prepared by adding 2.5 g of said modified psyllium to 50 g water, stirring the psyllium-water mixture for 30 seconds, allowing the stirred mixture to stand at room temperature for at least 3 hours, by using a double compression test with a pre-test speed of 0.2 mm per second, a test speed of 5.0 mm per second, a post test speed of 5.0 mm per second, a distance of 6 mm, and a probe diameter of 2.5 cm.

In another aspect of the invention there is provided a method for preparing an edible modified psyllium as described above comprising the steps of:

a) providing an acid solution containing an acid having a pKa of less than or equal to 5.0;

b) adding the acid solution of step a) to untreated raw psyllium husk having a purity of at least 85%;

c) reacting the acid solution with the raw psyllium husk for a period of time sufficient for the acid to modify at least a portion of the non-starch polysaccharides of the psyllium; and

d) removing the acid solution by one of centrifugation, evaporation, or filtration and recovering the edible modified psyllium.

In a further aspect of the invention there is provided a modified psyllium that does not form a gel when 2.5 grams of said modified psyllium is exposed to 50 grams of water.

In a particularly preferred embodiment, raw psyllium is treated with an acidic aqueous solution of a solvent and an acid. The solvent is capable of dissolving the acid and may be organic, inorganic or a mixture thereof. Ethanol is a preferred organic solvent.

The acid preferably is a moderate to strong acid, having a pKa of not greater than 5, preferably between about 1 and about 5, and most preferably between about 3 and about 1. In a preferred embodiment, the acid is hydrochloric acid.

It will be understood that the modified psyllium of the invention may also contain various byproducts of the reaction between the solution and the psyllium, e.g. mono-, di-, poly- and oligo-saccharides and the like that result from the treatment of the raw psyllium. The recovered modified psyllium may be directly added with other ingredients to prepare the desired end product, e.g. a psyllium-containing food product, or may be dried or freeze dried and stored for later use. Byproducts may also be isolated from the solution mixture and used as a separate ingredient or in another application as desired.

The modified psyllium has improved or extended functionality, e.g., a reduced water absorption rate, a decreased gel hardness, compared to the raw psyllium starting product. The modified psyllium has improved processing qualities over raw psyllium and is useful for, e.g. preparing foodstuffs, livestock feeds and pharmaceuticals. In a preferred embodiment, a 5% w/v solution of the modified psyllium in water exhibits no gel-formation.

In comparison to raw psyllium, upon hydration the modified psyllium of the present invention has a decreased rate of water absorption, and decreased gel hardness, adhesiveness, elasticity and sliminess, but preferably retains at least a portion, e.g. at least 10%, of the insoluble and soluble fiber content of the raw psyllium starting product. Since the modified psyllium retains at least a portion of its fiber content it can be substituted for raw or otherwise treated, e.g. pregelatinized psyllium to prepare improved food and pharmaceutical products compared to those of the prior art.

Other embodiments of the present invention is further described hereinbelow:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic of a preferred method of preparing modified psyllium according to the invention; and

Fig. 2 is a graph of the water absorbing properties of the modified psyllium of Example 3 versus raw psyllium.

DETAILED DESCRIPTION

The modified psyllium of the present invention may be prepared by reacting raw psyllium with an agent that modifies the non-starch polysaccharides of raw psyllium under conditions such that polysaccharide modification can take place. Suitable non-starch polysaccharide modifying agents include acids, e.g. hydrochloric acid and enzymes, e.g. xylanses. Suitable enzymes are described in the U.S. patent application filed on June 4, 1999 entitled ENZYMATIC MODIFICATION OF PSYLLIUM (Yu *et al.*), and published as U.S. Patent No. 6,248,373 on June 19, 2001 and incorporated herein by reference.

The modified psyllium of the present invention provides vastly improved manufacturing qualities compared to raw psyllium. The modified psyllium of the present invention preferably has modified properties, e.g. increased or decreased gel hardness compared to the raw psyllium starting product. Gel hardness is an indicator of the strength of the gel formed when psyllium is hydrated with water. Gel hardness is defined as the peak force during the first compression cycle measured using a TA-XT2 texture analyzer which is commercially available from Texture Technologies Corp., Scarsdale, New York, USA. All measurements are made on gels prepared by mixing 2.50 grams of the psyllium to be tested in 50 ml distilled deionized water. The test psyllium is added to the water and stirred for 30 seconds and then allowed to set for 3 hours, after which the formed gel is subjected to a double compression test. The measurements are performed using a test speed of 5.0 mm/sec at a distance of 6 mm.

In preferred embodiments, the modified psyllium tested as described above exhibits a gel hardness range from 5 to about 100% less than that of the starting raw psyllium, e.g. about 8.5% to about 90% less than raw psyllium. Preferably, the modified psyllium exhibits no measurable gel hardness, i.e. no gel is formed at all such that a gel hardness cannot be ascertained, up to a gel hardness of about 75 g. In other preferred embodiments, modified psyllium exhibits a gel hardness of from 0.05 to about 70 g, and preferably from about 1 to about 50 g. For purposes herein, psyllium which does not gel, i.e. for which a gel hardness cannot be

determined, shall be designated to have a gel hardness of less than 10 grams depending on the sensitivity of the texture analyzer.

Gel hardness of the modified psyllium can vary according with the intended end use. For example, if the modified psyllium is to be incorporated into a beverage or powdered drink mix, a very low gel hardness, e.g. 0 g to 30 g may be desired. For baked products such as muffins, snack bars or cookies, a relatively higher gel hardness may be acceptable, e.g. from 30 g to about 70 g. The desired gel hardness can be imparted to the psyllium by modifying various processing parameters such as those described in further detail hereinbelow. Gel hardness can also be increased, if desired.

In addition to having a decreased gel hardness compared to that of raw psyllium, the modified psyllium of the present invention will also preferably exhibit a lower water absorption rate compared to the starting raw psyllium product. Preferably, the modified psyllium of the invention will exhibit a decreased water absorption rate, a decreased elasticity, decreased adhesiveness, decreased sliminess or a combination of any of these compared to the raw psyllium starting product.

The present invention is also directed to a method for preparing the modified psyllium of the present invention. The modified psyllium of the invention is prepared by exposing raw psyllium to an agent that modifies non-starch polysaccharides of psyllium for a sufficient period of time to modify physical characteristics of the psyllium, e.g., to decrease the gel strength of the subsequently recovered product compared to that of the raw psyllium starting material. The agent that modifies non-starch polysaccharides of psyllium may be any compound that is capable of modifying the physical and chemical (physico-chemical) properties of psyllium, and more preferably the xylan backbone of psyllium polysaccharides. Therefore, there is no need to add, e.g., emulsifiers or edible acids, thus presenting a considerable advantage over previously suggested approaches. In a preferred embodiment, an agent that modifies non-starch polysaccharides of psyllium is an organic solvent. In other preferred embodiments, an agent that modifies non-starch polysaccharides of psyllium is an acid.

After treatment with an agent that modifies non-starch polysaccharides of psyllium, the modified psyllium is recovered by, e.g removing the solvent by evaporation or by separating the psyllium, e.g. by filtration.

In a preferred embodiment, the modified psyllium is prepared by treating raw psyllium with a solution comprising from about 1 to about 100% of a solvent and from about 0 to about 99% of an acid. The treatment is conducted for a sufficient amount of time and at suitable processing conditions such that the resultant psyllium has the desired predetermined properties, which will vary according to the intended use of the modified psyllium product. In a preferred embodiment, the psyllium is added to an acidic solution comprising an acid and a solvent, i.e. a solvent capable of dissolving the acid, and recovering the modified psyllium, e.g. by evaporation of the solvent.

The psyllium used as the starting material is preferably raw psyllium husk. Preferably, the psyllium is 98% pure, because this grade of psyllium is especially suited for use in the food and pharmaceutical industries. It may be preferable in certain instances to use a less pure psyllium, e.g. 85% pure, particularly if the end product will be used as a feed for farm animals. Thus, the starting product will vary with the end use of the final product.

The solvent can be any suitable aqueous or organic solvent, or mixtures thereof. Preferred organic solvents include alcohols such as C_1, to C_{20} alcohols or polyalcohols, preferably C_1 to C_5 alcohols. Suitable alcohols e.g. methanol, ethanol, propanol, and isopropyl alcohol. Ethanol is preferred.

Water is also a suitable solvent, and combinations of organic solvent and aqueous solvents are also useful. Other solvents that can be used in accordance with the present invention will be apparent to those skilled in the art.

The solvent is preferably present in an amount of from about 0.01% to about 100% of the solution. In a preferred embodiment, the solution is entirely comprised of the solvent.

In other preferred embodiments, the non-starch psyllium modifying agent includes an acid, and is preferably an solvent containing alcohol. The acid used may be any acid known in the art, although moderate to strong acids, and those having a pK_a of about 5 or less are particularly preferred. Acids with a pK_a of from about 3 to about 1 are particularly preferred.

The acid may be organic or inorganic. Preferably, the acid is an inorganic acid such as hydrochloric acid, sulfuric acid, nitric acid, phosphoric acid and the like. Hydrochloric acid is particularly preferred.

Preferred organic acids include acetic acid and halogenated acetic acids.

Preferably, the acid is present as from about 0.01 to about 99% w/v of the acidic solution. More preferably, the acid is present in an amount of from about 0.05% to about 50% w/v of the solution, and more preferably from about 0.10% to about 10% w/v.

The method of the present invention contemplates embodiments where the acid is added to a mixture of solvent and psyllium. It is also understood that the acid is preferably added as an solution of acid and a solvent, e.g. water, and such embodiments are considered to be within the scope of the present invention.

The psyllium is subjected to the acid treatment until the desired endpoints are met. The endpoints are preferably predetermined, and will be selected based upon the desired use of the end product. Typically, the acid treatment will be carried out overnight. Preferably, the acid treatment is carried out for a time period of about 1 hour to 7 days. Preferably, the time period ranges from about 12 to about 200 hours, and more preferably for about 50 to about 180 hours. The time period required will vary with the strength or concentration of the selected acid, the desired properties of the modified psyllium, and other factors that will be readily apparent to the skilled artisan.

Other processing conditions will vary depending on the desired end product. For example, the acid treatment may be suitably conducted at room temperature. Thus, the temperature is preferably above the freezing point of the solution but below the boiling point of the solution and at a temperature which will substantially degrade the psyllium and render the product unfit for use. It will be appreciated that generally an increase in reaction temperature generally correlates to an increase in the rate of acid hydrolysis of the xylan polysaccharide found in the psyllium. Generally, the acid treatment is conducted at from about 20° C to about 100°C. The appropriate temperature will be determined from a variety of factors, including the preferred rate of reaction, the preferred degree of modification of the psyllium, the concentration and type of acid used, and other factors that will be apparent to the skilled artisan.

The volume of acidic medium used is not critical, but should be a sufficient amount to totally immerse all of the psyllium in the acidic medium. A suitable amount of additional solvent may be added during the acid treatment to replace amounts lost to, e.g., evaporation, processing, etc.

During the acid treatment, it is contemplated that samples of product will be taken at various points in time and tested to see if the desired endpoints have been attained. Process

conditions may be modified during the course of the acid treatment to attain the desired end product. For example, more acid may be added or the temperature may be raised to account for intra- and inter-batch variations that may occur in the raw psyllium or in the reagents comprising the solvent.

After the desired endpoint is reached, the psyllium product is recovered. Recovery of the product may be by solvent evaporation, filtration, centrifugation, or other known methods. Solvent evaporation is preferred. The recovered product includes the modified starting psyllium husk and may also contain various reaction byproducts such as oligosaccharides, and along possibly along with acid salts that may form by reaction of psyllium components or other reaction byproducts. Thus, the term "psyllium product" as used herein refers to any product derived from treatment of the psyllium, or any portion or fraction thereof. Thus, it will be understood that there may be fractions of reaction by-products remaining in the solvent that may be separated when the solvent is removed. The present invention also contemplates these products to be within the scope of the invention.

In preferred embodiments, solvent evaporation is used to recover the modified psyllium. Solvent evaporation will retain both the psyllium and any degradation products in the final recovered product.

In other applications, it may be desirable to remove certain fractions from the final product, e.g. sugar hydrolysis products. In such instances, filtration may be preferred as unwanted fractions along with the solvent.

After recovery, the final product may be dried to a desired water content. The product may simply be air dried at room temperature, or it may be dried by heating in an oven at a temperature above ambient temperature until the desired water content is reached. The drying process is not critical to the invention, and it is contemplated that the recovered product may not be dried but rather directly incorporated with other ingredients to prepare useful psyllium-containing products. The product may also be freeze dried.

After recovery, the product may be milled to a desired particle size. Alternatively, the psyllium can be milled to the desired particle size prior to acid or solvent treatment.

It has been surprisingly discovered that the improved properties of the modified psyllium of the present invention allow inclusion of the entire recommended cholesterol-lowering dose, i.e. an amount sufficient to provide 7.0 grams of soluble fiber into a single 8 to 10 oz. beverage

serving. Reduced dosing frequency is generally known to increase patient compliance with a given dosing regimen, and will be an additional benefit provided by the modified psyllium of the present invention. In a preferred embodiment, a beverage prepared with the modified psyllium of the invention contains a sufficient amount of modified psyllium to provide approximately 7.0 grams of soluble fiber per 240 milliliters of beverage. It is preferred that the modified psyllium does not gel if it is to be used in a beverage or drink mix, or other liquid product, e.g. a bulk laxative drink mix.

The modified psyllium of the present invention can be formulated into a wide variety of products, including, e.g pharmaceuticals such as bulk laxatives, food products, drink mixes, beverages, animal feed, and the like using conventional techniques known to the skilled artisan. If the modified psyllium of the invention replaces a raw psyllium used in a prior art product, it should be understood that it may be necessary to reduce the amount of other ingredients that are used as processing aids, e.g. emulsifiers, edible acids, and other agents used to enhance processing with raw psyllium. It may also be necessary to adjust the amount of water during processing, since the modified psyllium of the present invention does not absorb as much water as raw psyllium.

Like raw psyllium, the modified psyllium of the present invention lowers serum cholesterol, triglycerides, provides a bulk laxative effect, and provides other beneficial health effects attributed to raw psyllium when the modified psyllium is administered in equipotent doses of soluble fiber to that of raw psyllium.

To lower serum cholesterol and/or LDL, to lower serum triglycerides, and to provide bulk laxation in a mammal, a sufficient amount of the modified psyllium of the invention will be orally administered a therapeutically effective amount of the provided psyllium of the invention to a mammal, preferably a human. The dose can be provided as a liquid, capsule, tablet, granule, or any other pharmaceutically acceptable dosage form. The dose may also be incorporated into the diet, or added as a food ingredient to make, e.g., snack foods, entrees, or any other suitable foodstsuff.

The following examples describe preferred embodiments of the invention. It will be understood that the examples provided herein are illustrative but do not limit the scope of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

General procedure

Eighty grams (80 g) of raw psyllium (98% purity, 40 mesh, commercially available from JB Laboratories) was dispersed in a solvent contained in a 1000 ml beaker. The required amount of concentrated hydrochloric acid (Sigma, 36%-38%, w/v) was added in above psyllium solution at ambient temperature (20-25 °C). The reaction was stopped by neutralizing the reacting solution to pH 6-7 using 10 M sodium hydroxide, after reacting for certain time period. The solvent was removed by filtration. The modified psyllium filtrate was collected and dried in air overnight, except Example 8. The final product of acid modification was obtained after grounding the dried material through a lmm sieve using Wiley Mill Grounder (Model ED-5, Arthur H. Thomas Co., Phila., PA).

Analytical methods for modifications of psyllium

Two tests for each psyllium, including water up-taking capacity and gelling properties, were performed to evaluate the functionality of enzymatically modified psyllium. In addition, fiber contents (both soluble and insoluble fiber) were measured, since soluble fiber might be associated with health benefits of psyllium, especially for laxative and hypocholesterol effects.

Soluble and insoluble fiber contents were measured using the lab protocol set forth by Lee et al., Journal of AOAC International, "Determination of Soluble and Insoluble Dietary Fiber in Psyllium-Containing Cereal Products," Vol. 78, No. 3, pp. 724-729 (1995).

Water absorbing capacity was determined gravimetrically according to the previous method described by Elizalde et al. Empirical model for water intake and hydration rate of food powders by sorption and Baumann methods, *Journal of Food Science* 61: 407-409 (1996), with some modification. Briefly, all samples were equilibrated in a 10% humidity chamber for 48 hours. Then, samples were transferred into a 65% humidity chamber and exposed to moisture for 5 min. The dry matter and the absolute amount of absorbed water were determined. All measurements were made in triplicate. The results were expressed as "mean + SD" in mg water absorbed by per gram of psyllium per minute (mg/g/min).

Gelling properties were analyzed using a TA-XT2 texture analyzer (Texture Technologies Corp., Scarsdale, NY) with a 1 inch diameter probe (Paraskevopoulou, A. and Kiosseoglou, V. (1997) Texture profile analysis of heat-formed gels and cakes prepared with low cholesterol egg yolk concentrations, *Journal of Food Science* 62: 208-211.). 2.50g of psyllium was added into

50 ml. distilled deionized water and stirred for 30 seconds. After setting for 3 hours, gel samples were subjected to a double compression test. Measurements were performed with a pretest speed of 2.0 mm/sec, a test speed of 5.0 mm/sec, a post test speed of 5.0 mm/sec, and a distance of 6 mm. All measurements were made in triplicate. Two and one-half grams (2.5 g) of 98% psyllium, 40 mesh, are added to 50 ml. of distilled water and this was used to compare the gelling and water-absorbing properties of modified psyllium. The results were expressed as "mean ± SD" in gram force for hardness and adhesiveness. All results are shown in Table 1 below.

Example 1

Eighty grams (80 g) of 98%, 40 mesh raw psyllium was added in 400 ml ethyl alcohol, and the mixture was kept at ambient temperature for 125 hours. The solvent was then removed and the resultant solid was air dried. The solid was ground through a 1 mm sieve.

Example 2

Eighty (80) grams of psyllium was dispersed into 388 ml of ethyl alcohol and 16 ml of HCl was added in the solution to make a final concentration of 1.6%. After 125 hours, the reaction was stopped.

Example 3

The psyllium was dispersed into 396 ml of ethyl alcohol and 8 ml of HCl was added in the solution to make a final concentration of 0.8%. After 125 hours, the reaction was stopped.

Example 4

The psyllium was dispersed into 400 ml of ethyl alcohol and 4 ml of HCl was added in the solution to make a final concentration of 0.4%. After 125 hours, the reaction was stopped.

Example 5

The psyllium was dispersed into 374 ml of ethyl alcohol and 32 ml of HCl was added in the solution to make a final concentration of 3.2%. After 125 hours, the reaction was stopped.

Example 6

The psyllium was added to 400 mls of iso-propanol and 4 ml HCl was added. The reaction was stopped after 96 hours.

Example 7

The psyllium was added to 400 ml ethyl alcohol, and 4 ml HCl was added. The reaction was stopped after 96 hours.

Example 8

The psyllium was mixed with 400 ml water and 10 ml HCl was added to the suspension. The reaction was stopped after 96 hours. After neutralization, the paste was freeze dried using a Genesis-25EL freeze drier (commercially available from The Virtis Company, Gardiner, NY) with the following temperature program: -40°C for 720 hrs, -20°C for 720 hrs; 0 °C for 720 hours; 10°C for 720 hours; 20 °C for 720 hours; and 25 °C for 720 hours.

TABLE 1					
Example No.	Soluble Fiber (%)	Insoluble Fiber (%)	Water uptake rate (mg/g/min.)	Hardness (g)	Adhesiveness (g)
1	71.42	14.19	2.39±0.09	73.66±5.40	18.15±2.10
2	62.48	10.91	1.31±0.03	18.86±1.19	2.90±0.76
3	69.75	11.17	1.68±0.09	36.98±1.95	6.73±0.26
4	68.74	12.65	1.76±0.03	63.48±1.92	13.30±0.80
5	53.26	5.69	1.22±0.02	ND[A]	ND
6	74.38	11.71	1.33±0.05	42.02±2.85	10.55±0.63
7	74.63	11.66	1.52±0.03	67.38±3.30	14.94±0.86
8	69.78	10.66	2.06±0.04	29.85±3.51	5.52±0.76
Control Example:- Raw psyllium*	74.30	14.42	2.17±0.04	81.70±3.15	19.68±0.92

ND[A] means the sample did not gel at a concentration of 5% w/v in H_2O

*The psyllium used was 98% psyllium, 40 mesh

Hardness and adhesiveness are the maximum force (g) measured on for peaks of the "texture profile" graph provided according to analytical testing with a texture analyzer as outlined above. These properties correspond to the first positive peak and the first negative peak.

The results show that more desirable functionality is achieved with the acid modified psyllium of the present invention compared to the control examples.

It is shown that improved functionality can be achieved when raw psyllium is exposed to an organic solvent alone. Also, no gel formation was observed for Example 4, a desirable result.

Example 9

To test the cholesterol lowering effect of the acid treated psyllium, studies were conducted using male LVG Golden Syrian hamsters from Charles River Canada.

In total, 5 groups of hamsters were studied. Following a 6 day acclimatization period, groups of 12 animals were fed one of five synthetically prepared diets for 3 weeks. The first two diets were control diets and were identical by formulation, with the exception that the first diet was without cholesterol, and the second diet had cholesterol. The third diet (Test 1) had raw psyllium as a test material, the fourth diet (Test 2) has low acid psyllium of Example 3 as a test material, and the fifth diet (Test 3) included high acid psyllium of Example 5 as a test material. The final diet preparations (after mixing) were analyzed for fat and protein content. The diets in tests 1-3 were the same as Control Diet 2 except for the addition of the test psyllium product. The diet formulas are shown in Table 2 below:

TABLE 2

	Control Diet 1 (w/o Chol.)	Control Diet 2 (w/Chol)	Test Diet 1 Raw Psyllium	Test Diet 2 Low Acid Psyllium	Test Diet 3 High Acid Psyllium
Invariable Ingredients					
DL-methinione	18	7.5	7.5	7.5	7.5
L-lysine	12	5	5	5	5
AIN Vit. mix	144	60	60	60	60
AIN Min. mix	480	200	200	200	200
Choline Cl	60	25.0	25.0	25.0	25.0
Coconut oil	240	100	100	100	100

Variable Ingredients					
Test Material	0	0	352.5	347	461
Wheat Bran	2880	1200	850	850	850
Casein (90.6%)	2160	900	900	900	900
Beef Tallow	840	350	350	350	350
Corn Oil	480	200	200	200	200
Cornstarch	2832	1180	1180	1180	1080
Sucrose	1716	715	715	715	715
Cholesterol	0	6.25	6.25	6.25	6.25
NaCl	83.2	34.7	34.7	34.7	34.7
Total Weight (g)	11945.2	4983.5	4986.0	4980.5	50.94.5

The test results are presented in Table 3 and represent a mean of two determinations.

TABLE 3

Group	Control Diet 1 w/o Cholesterol	Control Diet 2 w/ Cholesterol	Test 1 Raw Psyllium	Test 2 Low Acid Psyllium	Test 3 High Acid Psyllium
Total Fat Content (%)	17.0	15.7	16.5	16.7	15.1
Total Protein Content (%)	18.5	18.5	16.8	17.3	17.6

The test animals had ad libitum access to water and respective dietary formulations. The food consumption and body weight gains of the hamsters were determined twice weekly. At the end of the 3 week feeding period, and following an approximate 24 hour fasting period, the hamsters ere sacrificed by exsanguination under ketamine/rompun anaesthesia.

Blood was collected into serum vacutainers, the serums were separated, stored at 2-8°C and analyzed within 24 hours. The analysis included the determination of total triglycerides, total cholesterol and HDL-cholesterol.

All clinical and analytical data were recorded and their respective means and standard deviations were calculated. A summary of this data is shown in Table 4 with the use of group means.

TABLE 4

Group	Control Diet 1 w/o Cholesterol	Control Diet 2 w/ Cholesterol	Test 1 Raw Psyllium	Test 2 Low Acid Psyllium	Test 3 High Acid Psyllium
Total Food Consumption (g)	192 ± 16.3	199 ± 16.4	161.6 ± 16.2	172.9 ± 13.2	183.8 ± 10.3
Total Body Weight Gain (g)	27.7 ± 7.0	25.1 ± 7.6	16.1 ± 6.0	23.7 ± 6.3	25.4 ± 5.7
Triglycerides mmol/L	0.80 ± .017	0.90 ± 0.33	0.77 ± 0.07	0.83 ± 0.24	0.79 ± 0.19
Total Cholesterol mmol/L	3.6 ± 0.55	4.90 ± 0.55	3.36 ± 0.30	3.73 ± 0.31	4.31 ± 0.55
HDL Cholesterol mmol/L	0.74 ± 0.13	0.96 ± 0.15	0.58 ± 0.06	0.65 ± 0.08	0.77 ± 0.20

Chemistry analyses were done on the low and high-acid psyllium, and fiber contents were determined (raw: 75%, low-acid: 72%, high-acid: 54%). The amount of low-acid and high-acid psyllium in those respective diets was increased accordingly to make all psyllium diets identical in soluble dietary fiber content.

The raw psyllium group had cholesterol below that of the negative control; however, there was slightly lower food intake and weight gain in these animals, which may have lowered cholesterol in addition to the cholesterol lowering effects of psyllium. The low-acid psyllium group (fed to the fiber level of raw psyllium) had cholesterol 24% lower than the positive control, a level similar to the negative control group. The high-acid psyllium group, despite also being fed to the fiber level of raw psyllium, had cholesterol intermediate between the positive and negative control (12% lower than positive control).

The studies show that the modified psyllium of the present invention is effective in lowering serum triglycerides and serum cholesterol.

It will be understood that the specification and examples are illustrative of the present invention and that other embodiments within the spirit and scope of the invention will suggest themselves to those skilled in the art. All references cited herein are incorporated by reference.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form or suggestion that that prior art forms part of the common general knowledge in Australia.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Modified psyllium having a gel hardness of from 0 g to 75 g, wherein said gel hardness is measured after exposing a suspension prepared by adding 2.5 g of said modified psyllium to 50 g water, stirring the psyllium-water mixture for 30 seconds, allowing the stirred mixture to stand at room temperature for at least 3 hours, by using a double compression test with a pre-test speed of 0.2 mm per second, a test speed of 5.0 mm per second, a post test speed of 5.0 mm per second, a distance of 6 mm, and a probe diameter of 2.5 cm.

2. A food product containing the modified psyllium of claim 1.

3. A beverage comprising the modified psyllium of claim 1.

4. A powdered drink mix comprising the modified psyllium of claim 1.

5. An animal feed comprising the modified psyllium of claim 1.

6. A pharmaceutical product comprising the modified psyllium of claim 1.

7. A modified psyllium that does not form a gel when 2.5 grams of said modified psyllium is exposed to 50 grams of water.

8. A powdered drink mix comprising the modified psyllium of claim 7.

9. A beverage comprising a sufficient amount of the modified psyllium of claim 7 to provide approximately 7.0 grams of soluble fiber per 240 milliliters of beverage.

10. A method for preparing an edible modified psyllium as defined in claim 1 comprising the steps of:

a) providing an acid solution containing an acid having a pKa of less than or equal to 5.0;

b) adding the acid solution of step a) to untreated raw psyllium husk having a purity of at least 85%;

c) reacting the acid solution with the raw psyllium husk for a period of time sufficient for the acid to modify at least a portion of the non-starch polysaccharides of the psyllium; and

d) removing the acid solution by one of centrifugation, evaporation, or filtration and recovering the edible modified psyllium.

11. The method of claim 10, wherein step a) comprises providing an acid solution containing at least one of hydrochloric acid, sulfuric acid, nitric acid, phosphoric acid, acetic acid, or a halogenated acetic acid.

12. The method of claim 11, wherein step a) comprises providing an acid solution comprising hydrochloric acid.

13. The method of any one of claims 10 to 12, wherein step a) comprises providing the acid in the acid solution at a concentration of from 0.01 to 99.0% weight/volume.

14. The method of claim 13, wherein step a) comprises providing the acid in the acid solution at a concentration of from 0.05 to 50.0% weight/volume.

15. The method of claim 14, wherein step a) comprises providing the acid in the acid solution at a concentration of from 0.10 to 10.0% weight/volume.

16. The method of any one of claims 10 to 15, wherein step a) comprises providing an acid solution containing an acid having a pKa of from 1 to 3 inclusive.

17. The method of any one of claims 10 to 16, wherein step a) comprises the further step of preparing the acid solution by combining a solvent comprising at least one of water, a C_1 to C_{20} alcohol, or a C_1 to C_{20} polyalcohol with the acid.

18. The method of claim 17, wherein step a) comprises the further step of preparing the acid solution by combining a solvent comprising at least one of water, a C_1 to C_5 alcohol, or a C_1 to C_5 polyalcohol with the acid.

19. The method of claim 18, wherein step a) comprises the further step of preparing the acid solution by combining a solvent comprising ethanol with the acid.

20. The method of any one of claims 10 to 19, wherein step c) comprises reacting the acid solution with the psyllium at a temperature of from 20°C to 100°C.

21. The method of any one of claims 10 to 20, wherein step c) further comprises reacting the acid solution with the psyllium for a period of time from 1 hour to 7 days inclusive.

22. The method of claim 21, wherein step c) further comprises reacting the acid solution with the psyllium for a period of time of from 12 hours to 200 hours inclusive.

23. The method of claim 22, wherein step c) further comprises reacting the acid solution with the psyllium for a period of time of from 50 hours to 180 hours inclusive.

24. The method of any one of claims 10 to 23, wherein step c) further comprises reacting the acid solution with the psyllium for a period of time sufficient for the acid to hydrolyze at least a portion of the non-starch polysaccharides of the psyllium.

25. The method of claim 24, wherein step c) further comprises reacting the acid solution with the psyllium for a period of time sufficient for the acid to hydrolyze at least a portion of the non-starch xylan polysaccharides of the psyllium.

26. The method of any one of claims 10 to 25, wherein step c) is carried out for a period of time sufficient to reduce by 5 to 100% the gel hardness of a solution prepared from the modified psyllium when compared to the solution prepared from the psyllium prior to modification.

27. The method of any one of claims 10 to 26, comprising the further step of drying the recovered modified psyllium.

28. The method of claim 27, comprising the further step of milling the recovered modified psyllium.

29. The method of any one of claims 10 to 28, comprising the further step of neutralizing the acid in the acid solution after step c) and prior to step d).

30. The method of any one of claims 10 to 28, comprising the further step of altering the pH of the solution produced in step c) to a pH of from 6 to 7 inclusive prior to step d).

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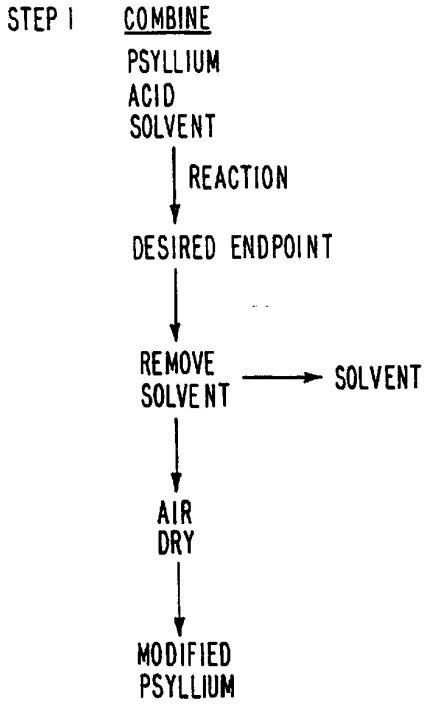
STEP I
COMBINE
PSYLLIUM
ACID
SOLVENT
REACTION
DESIRED ENDPOINT
REMOVE SOLVENT
SOLVENT
AIR DRY
MODIFIED PSYLLIUM

FIG. 1

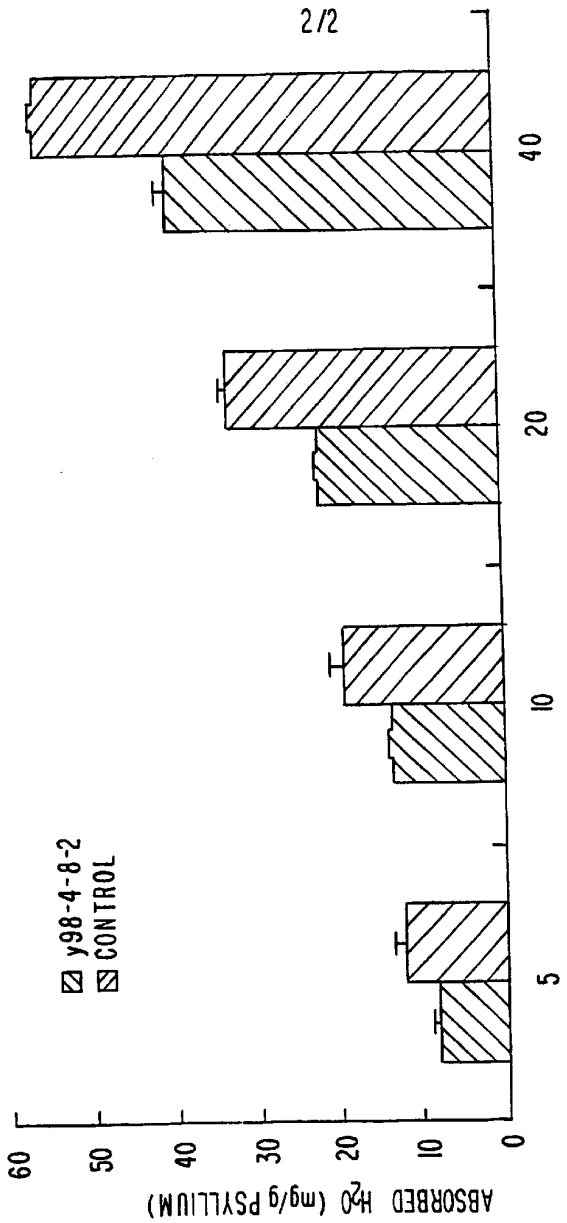

FIG.2

H_2O ABSORBING CAPACITY OF ACID TREATED PSYLLIUM