



- (51) International Patent Classification:  
A23L 1/305 (2006.01)
- (21) International Application Number:  
PCT/GB2014/051898
- (22) International Filing Date:  
20 June 2014 (20.06.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
1311027.5 20 June 2013 (20.06.2013) GB
- (71) Applicant: THE UNIVERSITY OF NOTTINGHAM [GB/GB]; University Park, Nottingham, Nottinghamshire NG7 2RD (GB).
- (72) Inventor: FOSTER, Timothy John; The University of Nottingham, University Park, Nottingham, Nottinghamshire NG7 2RD (GB).
- (74) Agent: BARKER BRETTELL LLP; First Floor, Atrium Court, 15-17 Jockey's Fields, London, Greater London WC1R 4BW (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

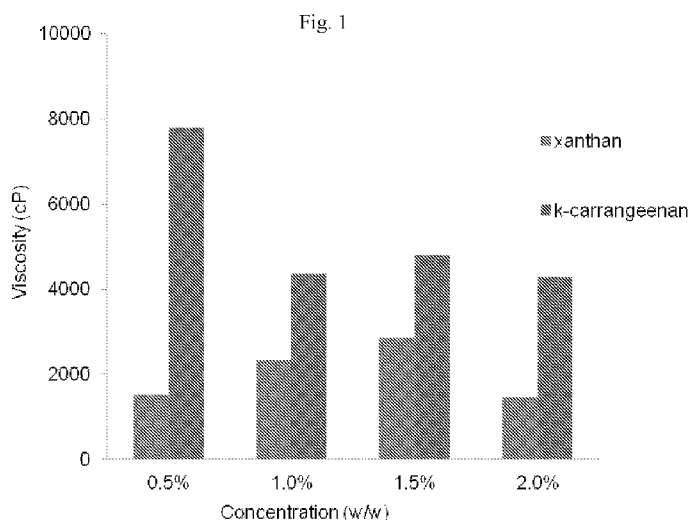
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CL, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: SATIETY GEL



(57) Abstract: The present invention relates to a composition comprising xanthan gum or κ-carrageenan, a swellable particulate and protein and/or a polysaccharide which forms a synergistic gel with xanthan and/or κ-carrageenan (e.g. galactomannan or glucomannan), and uses of such a composition, for example, to treat obesity. The present invention further relates to kits comprising said composition, wherein the composition is provided in separate first and second parts, and ranges of foodstuffs. The present invention also relates to a composition comprising κ-carrageenan and a swellable particulate. The present invention further relates to a method for forming an edible gel, gels so formed and uses for said gels, as well as food stuffs containing the compositions of the invention.



WO 2014/202997 A2

## Satiety Gel

### Field of the Invention

5

The present invention relates to a composition comprising xanthan gum or  $\kappa$ -carrageenan, a swellable particulate and protein and/or a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), and uses of such a composition, for example, to treat obesity. The present invention further relates to kits comprising said composition, wherein the composition is provided in separate first and second parts, and ranges of foodstuffs. The present invention also relates to a composition comprising  $\kappa$ -carrageenan and a swellable particulate. The present invention further relates to a method for forming an edible gel, gels so formed and uses for said gels, as well as food stuffs containing the compositions of the invention.

15

### Background to the Invention

The World Health Organisation (WHO) recognises that obesity is a major risk factor for a number of chronic diseases, including diabetes, cardiovascular disease and cancer. Once considered a problem only in high income countries, obesity is now dramatically on the rise in low- and middle-income countries, particularly in urban settings.

The WHO estimates that in 2008, more than 1.4 billion adults, aged 20 and older, were overweight. Of these over 200 million men and nearly 300 million women were obese. At least 2.8 million adults die each year as a result of being overweight or obese. In addition, 44% of the diabetes burden, 23% of the ischaemic heart disease burden and between 7% and 41% of certain cancer burdens are attributable to obesity.

30

There is, therefore, a pressing and ongoing need for effective ways for treating obesity.

A number of solutions have been suggested and are well known in the art, ranging from traditional calorie restricted diets and increasing exercise, to pharmaceuticals, gastric

operations and other medical interventions. However, these solutions are often unpopular with consumers and patients because they are seen as difficult to achieve, inconvenient, overly invasive or inherently risky.

- 5 An alternative strategy, which has attracted increasing interest in the last two decades, is to enhance satiety.

Satiety develops after food has been ingested. A state of satiety can lead to delays in the onset of hunger, and therefore the consumption of the next meal, as well as reducing the  
10 volume of food consumed at the next meal. It has been reported that control of satiety can play a significant role in weight management and therefore in public health.

The sensation of satiety is related to many factors, such as appearance, energy density, macronutrient composition, weight and volume, particle size, satisfaction and palatability  
15 of food.

WO2010/122332 describes a composition comprising at least about 0.2% w/w xanthan gum and at least about 6% w/w of a swellable particulate, and to uses thereof, including the treatment of obesity. The product continues to viscosify upon dilution, for example in the  
20 stomach, and may be used in nutritional/nutraceutical supplements for the control of the obesity.

There is, however, a need for foodstuffs which further enhance satiety, particularly in terms of duration.

25

The present invention addresses these and further problems with the prior art.

### **Summary of the Invention**

30 In a first aspect, the present invention provides a composition comprising at least about 0.05% w/w of xanthan gum or  $\kappa$ -carrageenan, at least about 2.5 % w/w of swellable particulate and preferably at least about 0.125 % w/w protein and/or at least about 0.02 %

w/w a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum. Typically, the food stuff forms a gel in water, for instance in the stomach. Preferably, the composition forms a gel in acidic pHs, in particular in those found in the stomach.

5

It has been discovered that the duration of satiety can be increased by the inclusion of protein in the composition of the invention. This effect is further enhanced by the inclusion of a polysaccharide known to form synergistic interactions with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum.

10

In a preferred embodiment the food stuff comprises from about 0.05 % w/w to about 3 % w/w of xanthan gum.

15

In an alternative embodiment, the food stuff comprises from about 0.05 % w/w to about 3 % w/w of  $\kappa$ -carrageenan.

20

In a further embodiment, the food stuff comprises from about 2.5 % w/w to about 15 % w/w of a swellable particulate, preferably swellable starch, preferably cross-linked waxy maize starch.

25

In a still further embodiment, the food stuff comprises from about 0.125 % w/w to about 15 % w/w of protein, typically the protein is an edible protein capable of supporting an oil in water emulsion, preferably wherein the protein is selected from the group consisting of animal milk proteins, preferably caseins, and plant milk proteins, preferably, soy, grain, rice, pea, potato, oil seed, meat (inc gelatin), fish, egg, algal, mycoprotein, hydrophobins and vegetable. In certain embodiment, proteins extracted from animal milk substitutes are particularly preferred.

30

In a further embodiment, the food stuff comprises from about 0.02 % w/w to about 1% w/w of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum. Typically, the polysaccharide is hydrated or readily hydratable in the composition.

In a second aspect, the present invention provides a kit for providing an edible gel. Typically, said kit comprises separate first and second parts. Preferably, when the first part and the second part are mixed they can form an edible gel. Typically, the first and second parts are different food stuffs.

Typically, the first part and second part are mixed in the presence of water. Alternatively, they may be mixed and then diluted with water, for instance in the stomach.

In a preferred embodiment, mixing may be achieved by ingesting the first and second part either sequentially or simultaneously.

In a third aspect, the present invention provides a range of food stuffs comprising a plurality of kits according to the second aspect of the invention. Typically, the first parts and second parts of each of the plurality of kits will form an edible gel with the other of the first parts and second parts of the kits making up the remainder of the range. That is, any first part will form an edible gel with a second part which forms part of the range.

In embodiments the invention provides a range of food stuffs for providing an edible gel in the stomach of an individual, said range comprising a plurality of separate first and second parts, wherein the first and second parts are different food stuffs, and wherein when any one of the first parts is mixed with any one of the second parts they can form an edible gel.

The second parts may be for instance different drinks, for instance juices, milk shakes or flavoured milks, sauces or soups and the first parts may be a snack-type food such as snack bars, breakfast bars, crisps, biscuits, noodles, pasta or bread.

In a fourth aspect, the present invention provides a method for providing an edible gel in the stomach of an individual comprising the steps of:

- a. providing a first part;
- b. providing a separate second part;
- c. mixing the first and second parts; and

- d. forming a gel from the resulting mixture.

Typically, the first part and second part are different food stuffs.

- 5 Typically, the first part and second part are mixed in the presence of water. Alternatively, they may be mixed and then diluted with water, for instance in the stomach.

In an embodiment of any of the aspects of the invention the mixing step is performed in the mouth, stomach, or immediately prior to ingestion. Immediately prior to ingestion  
10 preferably means less than five minutes before ingestion, preferably less than one minute before ingestion.

In a preferred embodiment, mixing may be achieved by ingesting the first and second part either sequentially or simultaneously.

15

By performing the mixing step in the mouth, stomach, or immediately prior to ingestion, the consumer may avoid having to eat a gel, which some may find unpleasant or unusual. Preferably, substantially all gelling occurs in the stomach. In this way, the consumer is unaware of the gelling taking place.

20

In preferred embodiments, the first part is a solid food stuff and the second part is a liquid food stuff.

In alternative embodiments both the first part and the second part are solid food stuffs. In a  
25 preferred embodiment, the first part or second part is a coating on the other of the first and second part. In a still further alternative embodiment both the first part and the second part are liquid food stuffs. In a still further embodiment the first part is a liquid food stuff and the second part is a solid food stuff.

- 30 The two parts of the kit may be packaged in separate compartments of the same item of packaging, or packaged as separate items. As discussed above, the kit may form part of a

range comprising a plurality of first parts and second parts, wherein first parts and second parts from the same range may be selected and used together to form an edible gel.

5 The kit has the advantage of providing a food stuff which is recognisable and attractive to the consumer, and provides a simple and consumer friendly delivery mechanism.

10 In the second, third and fourth aspects typically the first part comprises at least about 0.05% w/w<sub>kit</sub> (% w/w<sub>kit</sub> is the percentage by weight of the combined first part and second part, i.e. the composition as a whole) of xanthan gum or  $\kappa$ -carrageenan and at least about 2.5 % w/w<sub>kit</sub> of swellable particulate.

15 In a preferred embodiment the first part comprises from about 0.05 % w/w<sub>kit</sub> to about 3 % w/w<sub>kit</sub> of xanthan gum. In an alternative embodiment, the first part comprises from about 0.05 % w/w<sub>kit</sub> to about 3 % w/w<sub>kit</sub> of  $\kappa$ -carrageenan.

In a further embodiment, the first part comprises from about 2.5 % w/w<sub>kit</sub> to about 15 % w/w<sub>kit</sub> of a swellable particulate, preferably swellable starch, preferably waxy maize starch.

20 Typically the second part comprises at least about 0.125 % w/w<sub>kit</sub> protein. In a still further embodiment, the second part comprises from about 0.125 % w/w<sub>kit</sub> to about 15 % w/w<sub>kit</sub> of protein.

25 As discussed above the inclusion of protein increases the level of structure achieved by the resulting gel.

Preferably, the second part comprises at least about 0.02 % w/w<sub>kit</sub> to about 1% w/w<sub>kit</sub> of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum.

30 In a fifth aspect the invention provides a composition comprising at least about 0.05% w/w of  $\kappa$ -carrageenan and at least about 2.5 % w/w of a swellable particulate. Typically, the composition comprises at least about 2.5 % w/w of swellable particulate and at least about

0.125 % w/w protein. Typically, the food stuff further comprises at least about 0.02 % w/w of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum. Typically, the food stuff forms a gel in water, for instance in the stomach.

5

In preferred embodiments of all aspects of the invention, the swellable particulate is swellable at a temperature below about 60°C, preferably below about 37°C, more preferably the swellable particulate is swellable in a solution at room temperature. Room temperature may be about 25°C.

10

Preferably, the swellable particulate may be referred to as a cold swelling particulate.

A swellable particulate refers to a particulate that swells at least in water, but typically in other liquids or solutions.

15

Preferably the swellable particulate is readily dispersible in water. Preferably the swellable particulate is readily dispersible in other potable liquid or foodstuff, such as orange juice or milk.

20 The swellable particulate may comprise polymer molecules that have been stabilized in the particulate form by either chemical or physical cross-linking. Alternatively, or additionally, the swellable particulate may comprise a starch polymer which has been pre-gelatinised, which when dispersed in cold water produces swollen particles. The polymer molecules may be charged or uncharged. The polymer may be starch.

25

The swellable particulates may be of any suitable porosity or density.

Preferably, the swellable particulate swells to compete for water with polymeric, non particulate, xanthan gum or  $\kappa$ -carrageenan.

30

Preferably the xanthan gum or  $\kappa$ -carrageenan is not in particulate form once dispersed in cold water.

Preferably the swellable particulate would form a sediment layer when diluted, this in contrast to a polymeric solution that would form a more dilute solution when diluted.

- 5 In the composition of the invention the xanthan gum or  $\kappa$ -carrageenan may be driven/trapped in a highly concentrated anisotropic solution wherein the xanthan gum or  $\kappa$ -carrageenan is hydrated into a concentrated liquid crystalline phase.

The swellable particulate may comprise one or more of the following: starch, modified  
10 starch, citrus fibres, particulate xanthan gum (such as hydraxan), fibrous cellulose (such as nata de coco), oats, swellable gel particles e.g. dried fluid gel particulates created as described in Norton, Jarvis and Foster, International Journal of Biological Macromolecules (1999), 26, 255-261, or particulates described in WO9512988-A and surfactant micelles. Where the swellable particulate comprises of starch. The starch may be derived from  
15 potato, maize, tapioca, rice, wheat, cassava, pea or any other suitable material. The starch may be physically or chemically modified. If maize starch is used the maize starch may be a modified waxy maize starch. Preferably if starch is used it is a starch capable of being hydrated at below 60°C. Preferably the starch is not a cook-up starch.

20 This aspect of the invention is particularly applicable to the composition of the invention which is able to increase or maintain viscosity upon dilution, this would, for example, allow a product to continue to viscosify upon dilution in the stomach and thus lead to a feeling of greater satiety.

25 According to another aspect the present invention provides an edible gel formed from the composition, kit, range or using the method of any preceding aspect or embodiment of the invention. Preferably the edible gels increase in viscosity over the first two hours, preferably first four hours after ingestion.

30 According to another aspect the present invention provides the composition, kit, range or edible gel of any preceding aspect or edible gel formed using the method of any preceding aspect for use in the treatment of obesity.

In an embodiment of the invention the edible gel comprises at least about 0.05 % w/w of xanthan gum or  $\kappa$ -carrageenan, at least about 0.02% w/w of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (preferably locust bean gum); at least  
5 about 0.125% w/w of an edible protein which is able to support an oil in water emulsion; and at least about 2.5 % w/w of swellable particulate.

According to another aspect the present invention provides the use of the composition, kit, range or edible gel of any aspect or edible gel formed using the method of any preceding  
10 aspect to treat obesity; preferably wherein the composition, kit, range, edible gel or edible gel formed using the method of any preceding aspect is used at least once per day, preferably one to five times per day, most preferably three times per day, preferably at every meal.

15 It will be appreciated that, where appropriate, all optional or preferable features applicable to one aspect of the invention can be used in any combination, and in any number. Moreover, they can also be used with any of the other aspects of the invention in any combination and in any number. This includes, but is not limited to, the dependent claims from any claim being used as dependent claims for any other claim in the claims of this  
20 application.

### **Brief Description of the Figures**

The above-mentioned and other features and objects of this invention, and the manner of  
25 obtaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying figures, wherein:

Fig. 1 shows the initial viscosity of the xanthan and  $\kappa$ -carrageenan compositions.

30

Fig. 2 shows the viscosity of digested mixtures from 0-4 hours.

Fig. 3a-3d show the highest viscosity of samples with different milk types, but the same 1.5% xanthan composition, and control samples during digestion.

Fig. 4 shows the highest viscosity obtained at the end of measuring by the Rapid Visco  
5 Analyser (RVA) in the presence of two different types of milk mixture, A0 and B0, in the presence of xanthan compositions ranging from 0.5% to 1.5%, together with the highest viscosities achieved by the xanthan compositions alone, prior to dilution with milk.

Fig. 5 shows the highest viscosities obtained at the end of measuring with the RVA in the  
10 presence of two types of milk mixture, A0 and B0, in the presence of the  $\kappa$ -carrageenan compositions ranging from 0.5% to 1.5%.

Fig. 6 shows the highest viscosity obtained at the end of measuring with the RVA of  
15 digested samples (differing milk mixtures, A0 and B0) and controls (gastric juice replaced with water).

Fig. 7 shows the highest viscosity obtained at the end of measuring with the RVA of  
20 digested samples (differing milk mixtures, A1, A0, B1 and B0) and their controls (milk without LBG).

Fig. 8 shows the viscosities of different combinations of milk and cereal bars containing xanthan and swellable particulates in the model stomach system.

Fig. 9 shows the viscosities of combinations of milk with similar phase concentration but  
25 different protein:polysaccharide phase volumes, and cereal bars +/- xanthan and swellable particulates in the model stomach system.

Fig. 10 shows the viscosities of combinations of milk with similar phase volume ratio but  
30 different phase concentrations and cereal bars +/- xanthan and swellable particulates in the model stomach system.

Fig. 11 shows the range of viscosities when the starch, xanthan gum, locust bean gum and protein concentrations are varied in an example kit.

5 Fig. 12 shows the pasta consumption at the *ad libitum* meal; columns show the group means, lines indicate individual data for each subject (826 = test group, 473 = control group).

### 10 Detailed Description of the Invention

10

The present invention provides a food stuff composition comprising at least about 0.05% w/w of xanthan gum or  $\kappa$ -carrageenan, at least about 2.5 % w/w of swellable particulate and protein and/or a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan, preferably locust bean gum. Typically, the food stuff forms a gel in water, for  
15 instance in the stomach.

Unless explicitly stated otherwise, for the purpose of the invention, all percentages disclosed herein are by weight.

20 Xanthan gum is a polysaccharide, derived from the bacterial coat of *Xanthomonas campestris*, used as a food additive and commonly used as a food thickening agent (in salad dressings, for example). It is produced by the fermentation of glucose, sucrose, or lactose by the *Xanthomonas campestris* bacterium.

25 Carrageenans are a family of linear sulfated polysaccharides that are extracted from red seaweeds. They are widely used in the food industry, for their gelling, thickening and stabilizing properties. Their main application is in dairy and meat products, due to their strong interactions with protein. There are three main varieties of carrageenan, which differ in their degree of sulfation.  $\kappa$ -carrageenan has one sulfate per disaccharide repeat.

30

Synergistic gel forming water soluble polysaccharides suitable for the invention are typically those with a  $\beta$ 1,4 linked main chain, primarily galactomannans (polysaccharides consisting of a mannose backbone with galactose side groups (more specifically, a (1-4)-

linked beta-D-mannopyranose backbone with branch points from their 6-positions linked to alpha-D-galactose, i.e. 1-6-linked alpha-D-galactopyranose)) with favourable galactose:mannose, such as LBG (1:4), tara gum (1:3) and enzyme modified guar, and glucomannans such as konjac glucomannan. Typically, the synergistic gel forming water soluble polysaccharide forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan). Typically, when compositions comprise of xanthan, the polysaccharide should form a synergistic gel with xanthan, and when compositions comprise  $\kappa$ -carrageenan the polysaccharide should form a synergistic gel with  $\kappa$ -carrageenan.

Typically, the protein is an edible protein capable of supporting an oil in water emulsion, preferably wherein the protein is selected from the group consisting of animal milk proteins, preferably caseins, and plant milk proteins, preferably, soy, pea, grain, rice, pea and potato. In certain embodiment, proteins extracted from animal milk substitutes are particularly preferred. Edible typically means suitable for human consumption.

Typically, the food stuff composition comprises from about 0.05 % w/w to about 3 % w/w of xanthan gum, preferably from about 0.3 % w/w or from about 0.5 % w/w or from about 1 % w/w to about 2.5 % w/w or 2.0 % w/w.

Preferably, the food stuff composition comprises from about 0.05 % w/w to about 3 % w/w of  $\kappa$ -carrageenan, preferably from about 0.4 % w/w or from about 0.5 % w/w or from about 1 % w/w to about 2.5 % w/w or 2.0 % w/w.

Typically, the food stuff composition comprises from about 2.5 % w/w to about 15 % w/w, preferably from about 5 % w/w to about 10 % w/w, of a swellable particulate, preferably swellable starch, preferably cross linked waxy maize starch.

Preferably, the food stuff comprises from about 0.125 % w/w to about 15 % w/w, preferably from about 1 % w/w to about 10 % w/w, of protein.

The food stuff typically comprises from about 0.02 % w/w to about 1% w/w of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan (e.g. galactomannan or glucomannan), preferably locust bean gum.

- 5 The exact content of the compositions may be adjusted depending on the duration of satiety required.

The present invention also provides a kit for providing an edible gel. For the purposes of this application edible it is meant that the gel is fit for human consumption, rather than denoting that gel is eaten per se. As will be apparent, the gel may be formed in the stomach following ingestion, the gel itself having not been eaten.

Typically, the kit comprises separate first and second parts. Preferably, when the first part and the second part are mixed they can form an edible gel. They may either form a gel immediately upon mixing or following the addition of further water if there is insufficient present in the first or second parts. Typically, the first and second parts are different food stuffs, for instance a solid food and a drink, or a solid food and a sauce.

For the avoidance of doubt, foodstuff for the purposes of the invention includes drinks: i.e. solid and liquid foodstuffs. Pastes are also included.

Typically, the first part and second part are mixed in the presence of water. Alternatively, they may be mixed and then diluted with water, for instance in the stomach. Typically, the viscosity of the gel will increase upon dilution.

Preferably, the kits and compositions of the invention will form a gel at a pH of less than 7, preferably at a pH from about 1 to about 5, preferably at from about 2 to about 3, most preferably at a pH of 2.5.

Preferably, mixing may be achieved by ingesting the first and second part either sequentially or simultaneously. Typically, mixing will take place in either the mouth or stomach. Alternatively, the mixing may occur immediately prior to ingestion.

By performing the mixing step in the mouth, stomach, or immediately prior to ingestion, the consumer may avoid having to eat a gel, which some may find unpleasant or unusual. Preferably, substantially all gelling occurs in the stomach. In this way, the consumer is  
5 unaware of the gelling taking place.

The present invention provides a method for providing an edible gel in the stomach of an individual comprising the steps of:

- a. providing a first part;
- 10 b. providing a separate second part;
- c. mixing the first and second parts; and
- d. forming a gel from the resulting mixture.

Typically, the first part and second part are different food stuffs.  
15

Typically, the first part and second part are mixed in the presence of water. Alternatively, or additionally, they may be mixed and then diluted with water, for instance in the stomach. Alternatively, or additionally, the first or second part may include sufficient water to form a gel.  
20

In an embodiment of any of the aspects of the invention the mixing step is performed in the mouth, stomach, or immediately prior to ingestion. Mixing may be achieved by ingesting the first and second part either sequentially or simultaneously.

25 Typically, the first part is a solid food stuff and the second part is a liquid food stuff.

In alternative embodiments both the first part and the second part are solid food stuffs. In a preferred embodiment, the first part or second part is a coating on the other of the first and second part. In a still further alternative embodiment both the first part and the second part  
30 are liquid food stuffs. In a still further embodiment the first part is a liquid food stuff and the second part is a solid food stuff.

In a preferred embodiment, the kit may be provided in the form of a food with an accompanying drink. For instance a breakfast bar with a milk drink or a snack bar with a juice drink. Alternatively, the kit may be provided in the form of accompanying foods such as chips and dips; yoghurt with sprinkles; soup and croutons; pasta parcels with pasta sauce; ice cream and flake.

The two parts of the kit may be packaged in separate compartments of the same item of packaging, or packaged as separate items. The kit may form part of a range comprising a plurality of first parts and second parts, wherein first parts and second parts from the same range may be selected and used together to form an edible gel.

The kit has the advantage of providing a food stuff which is recognisable and attractive to the consumer, and provides a simple and consumer friendly delivery mechanism.

Preferred first parts include breakfast bars, snack bars, ready meals, pastry, cereals, pasta/pasta parcels, snack products, bread, morning goods, sausages, burgers, tinned products, chips, croutons, biscuits, sprinkles, dried foods, noodles.

Preferred second parts include milk drinks, yoghurt drinks, juice drinks, milkshakes, ice creams, frozen yogurts, soups, sauce, dips, yoghurt or cream coatings or fillings.

In the kit aspects the first part comprises at least about 0.05% w/w<sub>kit</sub> of xanthan gum or κ-carrageenan and at least about 2.5 % w/w<sub>kit</sub> of swellable particulate. The first part may form a gel in the absence of the second part; however, its effect on satiety will be less pronounced.

In the kit aspects the first part comprises from about 0.05 % w/w<sub>kit</sub> to about 3 % w/w<sub>kit</sub> of xanthan gum. In an alternative embodiment, the food stuff comprises from about 0.05 % w/w<sub>kit</sub> to about 3 % w/w<sub>kit</sub> of κ-carrageenan.

In a further embodiment, the first part comprises from about 2.5 % w/w<sub>kit</sub> to about 15 % w/w<sub>kit</sub> of a swellable particulate, preferably swellable starch, preferably cross-linked waxy maize starch.

- 5 In the second and third aspects typically the second part comprises at least about 0.125 % w/w<sub>kit</sub> protein. In a still further embodiment, the food stuff comprises from about 0.125 % w/w<sub>kit</sub> to about 15 % w/w<sub>kit</sub> of protein.

10 As discussed above the inclusion of protein increases the level of satiety achieved by the resulting gel.

Preferably, the second part comprises at least about 0.02 % w/w<sub>kit</sub> of a polysaccharide which forms a synergistic gel with xanthan and/or κ- carrageenan, preferably locust bean gum.

15

The invention provides a composition comprising at least about 0.05% w/w of κ-carrageenan and at least about 2.5 % w/w of a swellable particulate. Typically, the composition comprises at least about 2.5 % w/w of swellable particulate and at least about 0.125 % w/w protein. Typically, the food stuff further comprises at least about 0.02 % w/w

20 of a polysaccharide which forms a synergistic gel with xanthan and/or κ-carrageenan., preferably locust bean gum. Typically, the food stuff forms a gel in water, for instance in the stomach.

The invention will now be exemplified by the following non-limiting examples.

25

### **Example 1**

This example investigated the interactions between xanthan gum and κ-carrageenan compositions comprising waxy maize starch, with milk containing locust bean gum.

30

Two kinds of polysaccharides have been used which are xanthan gum (GRINDSTED XANTHAN CLEAR SUPRA, DANISCO France) and  $\kappa$ -carrageenan (DANISCO, Denmark).

## 5 Xanthan Composition

To make 100 g Xanthan composition

Ingredient	Amount (g)
Xanthan Gum	0.5 – 1.5
Starch	15
Oil	5
salt	0.58
Water	78.92 - 77.92

The oil, starch, salt and xanthan gum were mixed together by hand to form an oily powder and then the water was added with stirring for 1 min.

The starch chosen was cold water swelling cross linked waxy maize starch(UT2)(ULTRA-TEX 2, National Starch).

All the xanthan compositions were made in the presence of sodium chloride concentration of 0.1M (Sigma-Aldrich Company Ltd., United Kingdom) and with a constant concentration of 5% sunflower oil (Sainsbury's Supermarkets Ltd, UK).

The oil, starch and salt were roughly mixed in advance to an oily powder. After that, the water was added into the mixed powder and mixed for 1 min to mix the paste thoroughly.

Initial viscosity was measured by Rapid Visco Analyzer (RVA) (New Port Scientific, Australia) under constant temperature which was 25°C, and 180rpm shear rate for a total period of 20 minutes.

### $\kappa$ -carrageenan Compositions

To make 100 g  $\kappa$ -carrageenan composition

Ingredient	Amount (g)
$\kappa$ -carrageenan	0.5 - 2
Starch	15
Oil	5
salt	0.58
Water	78.92 - 77.42

- 5 The oil, starch and salt were mixed together by hand to form an oily powder and then the water and  $\kappa$ -carrageenan were added with stirring for 1 min.

The  $\kappa$ -carrageenan compositions were made in the presence of a cold water swelling waxy maize starch (UT2) at 15%.

10

A range of concentrations of  $\kappa$ -carrageenan were used which ranged from 0.5% - 2.0% (w/w) for  $\kappa$ -carrageenan in the final composition.

15

Initial viscosity was measured after the ingredients were added together by RVA at a constant temperature of 25°C, and 180rpm shear rate for a total period of 30 minutes.

Figure 1 shows the average viscosity of compositions with cold water swelling waxy maize starch (UT2). It appears that with same concentration of  $\kappa$ -carrageenan and xanthan by weight in the composition, the  $\kappa$ -carrageenan compositions always have higher viscosities.

20

The 0.5%  $\kappa$ -carrageenan composition reached a viscosity of 7795.698cP whereas a viscosity of 1514.39cP was achieved when using xanthan at the same concentration. The viscosity of xanthan composition increased when the concentration of xanthan increased until at 1.5% where it reached a peak viscosity (2844.770cP), and then dropped to

25

1459.151cP at a 2.0% xanthan concentration.

## Milk Preparation

To make 30 ml Milk drink

Sample	Skimmed Milk Powder (g)	Locust Bean Gum (g)	Water (g)
A0	25.38	6	0
A1	23.07	4.2	2.73
B0	6.92	15	8.08
B1	8.31	9.6	12.1

5 Milks were made from a mixture of skimmed milk powder (SMP) (Brakes England), locust bean gum (LBG 246, DANISCO) and water. The skimmed milk powder purchased from Brakes has a protein content of 12.2%. Typically the protein portion of skimmed milk powder contains approximately 80% casein (B. T. O’Kennedy, Handbook of food proteins, Woodhead Publishing, 2011). There were two kinds of methods to make the milk.

10

The SMP suspension was prepared by dispersing the skimmed milk powder into distilled water and stirred by a paddle mixer 600rpm per minute under a constant temperature of 60°C for 30 minutes to form a final concentration of 50% SMP (w/w). The LBG solution was obtained by diluting 1% LBG (w/w) in distilled water and stirring by a paddle mixer at 15 600rpm per minute under a constant temperature of 80°C for 30 minutes (Sanchez, 2000; Schorsch, 1999).

Four combination types of casein and LBG concentration in the milk mixture were chosen. They were A<sub>0</sub> (4.93% casein, 0.2% LBG), A<sub>1</sub> (4.69% casein, 0.14% LBG), B<sub>0</sub> (1.41% casein, 0.5% LBG) and B<sub>1</sub> (1.69% casein, 0.32% LBG). The weight of SMP suspension and LBG solution was calculated according to the concentration of the casein and LBG needed in the final milk mixture. After that, the appropriate weight of SMP suspension and LBG solution was mixed by a paddle mixer for 30 minutes under room temperature and the concentration was adjusted by adding distilled water or evaporating the extra moisture.

25

## Model Stomach

### Gastric juice buffer preparation

- 5 The gastric juice was prepared with 49mM NaCl, 3.6mM CaCl<sub>2</sub>, 1.5mM MgCl<sub>2</sub>, 12mM KCl, and 6.4mM KH<sub>2</sub>PO<sub>4</sub>, all purchased from Sigma-Aldrich Company Ltd., United Kingdom and pepsin. Pepsin used was from porcine gastric mucosa (Sigma-Aldrich Company Ltd., United Kingdom).

### 10 In-vitro simulation

To simulate digestion in stomach, the samples containing 3.125g of 1.5% xanthan thixate, 12.5g of milk mixture and 7.5g gastric juice were mixed roughly and incubated at 37°C and a stir rate of 130rpm in incubator for four hours.

15

### Viscosity of digested mixture

Samples were taken after digesting for 1h, 2h, 3h and 4h and their viscosity was measured by RVA at 25°C and shear rate of 180rpm for 14 minutes, immediately after removal from the incubator.

20

Fig. 2 shows the viscosity of the digested mixture of 3.125g 1.5% xanthan thixate, 7.5g gastric juice and 12.5g different kinds of milk mixtures after 1hour, 2hours, 3hour and 4 hours. The 0 hour viscosities of these samples are the initial viscosities. The milk mixtures used are respectively A0 (4.93% casein, 0.2% LBG), A1 (4.69% casein, 0.14% LBG), B0 (1.41% casein, 0.5% LBG) and B1 (1.69% casein, 0.32% LBG).

25

It can be seen from Fig. 2 that after digestion, the viscosity would rise in the stomach. Samples A0 and A1, which are casein rich milks, achieved a higher viscosity of 2035cP and 1483cP respectively than sample B0 and B1 which used LBG rich milk.

30

Fig. 3 a-d shows the viscosity information about digested mixtures prepared with four different casein and LBG concentration combination milks (made by mixing suspension of SMP and solution of LBG). The figures include controls for 7.5g gastric juice and 15.625g milk mixture, where the 3.125g xanthan composition was replaced with the same weight of milk mixture to give the same final weight.

Fig. 3a-d show that all the samples with the xanthan composition achieved higher viscosities than those the controls. This shows that the xanthan composition plays an important role in raising the viscosity of the digested mixture.

From Fig. 3a and 3b, it is shown that the xanthan composition makes the protein gel more viscous. This may be because a network is formed by casein and the polysaccharide.

Fig. 4 shows the highest viscosity obtained at the end of measurement with the RVA in the presence of two different types of milk mixture A<sub>0</sub> and B<sub>0</sub>, in the presence of the xanthan composition ranging from 0.5% to 1.5%, together with the highest viscosity obtained by the xanthan composition alone, prior to dilution with milk.

In the samples used in the model stomach, as the concentration of xanthan in the xanthan composition increases, the viscosity of digested mixture rises.

Fig. 5 shows the highest viscosities obtained at the end of measuring by the RVA in the presence of two types of milk mixture, A<sub>0</sub> and B<sub>0</sub>, in the presence of  $\kappa$ -carrageenan compositions ranging from 0.5% to 1.5%  $\kappa$ -carrageenan.

Fig. 6 indicates the highest viscosity of samples after digestion in the model stomach for a period of time (4 hours) in presence of protein rich milk A<sub>0</sub> and LBG rich milk B<sub>0</sub>. Controls with 7.5g of water replacing the 7.5g of gastric juice are also shown.

The viscosities of those with gastric juice samples are much higher than those in the aqueous control. This suggests that the low pH in gastric juice leads to a higher viscosity.

Fig. 7 shows the highest viscosity of samples after digestion in the model stomach for a period of time (4 hours) in the presence of 1.5% xanthan composition. Each group in the figure use the same milk mixture and all four different types of milk mixture were studied.

- 5 It can be seen that milk mixtures without LBG cannot achieve viscosities as high as those with LBG.

### Example 2 Cereal Bar and Milk Drink

#### 10 Cereal Bar Preparation

	<b>Ingredients</b>	<b>Weight / g</b>
Hydrocolloid starch system	Xanthan gum	1
	Cross linked waxy corn starch	5
	Vegetable Oil	2.5
Sugar	Golden Syrup	20
Oil	Vegetable Oil	10
Cereals	Whole grain oats	30

15 The whole grain oats (Nordwaldtaler), golden syrup (Tate & Lyle, Notts), butter (Morning fresh farm) and vegetable oil (Sainsbury's Supermarkets Ltd, United Kingdom) were all purchased commercially. Crossed linked waxy corn starch (Ultra Tex 2, National Starch Corporation) and xanthan gum (Xanthan Clear Supra, GRINDSTED®, Danisco, France) were food grade. Vegetable oil (Sainsbury's Supermarkets Ltd, United Kingdom) was purchased commercially.

20

To make the cereal bars, the hydrocolloid starch system was dispersed in vegetable oil first and mixed with the cereal base. Syrup was put in a saucepan and heated for 90s to 110°C, while being stirred occasionally. Hot syrup was poured in to the mixture of cereal and hydrocolloid starch system. All the ingredients were mixed well. The oat mixture was  
25 transferred to the prepared cake tin and spread to about 2cm (¾in) thick. The surface was

smoothed with the back of a spoon. They were baked in a preheated oven at 160°C for 12 minutes, until lightly golden around the edges, but still slightly soft in the middle. Finally, the cereal bars were cooled at room temperature for at least 2 hours before cutting.

## 5 Milk Preparation

Skimmed milk powder was from Brakes (England). Locust bean gum (LBG) was from Sigma®.

10 LBG solutions were prepared by dispersing LBG (1% w/w) in distilled water at 80°C while stirring with a magnetic stirrer at 1000rpm for 30min. Reconstituted milk was prepared by dispersing skimmed milk powder (SMP) (50% w/w) in distilled water at 60°C while stirring with a magnetic stirrer at 1000rpm for 30min. Milk containing LBG with different compositions were prepared by mixing LBG solution and reconstituted milk at room  
15 temperature for 30min while stirring at 1000rpm.

B1 = 1.69 % w/w casein and 0.32 % LBG

B0 = 1.41 % w/w casein and 0.50 % LBG

A1 = 4.69 % w/w casein and 0.14 % LBG

20

## Gastric Juice for Experiment

Buffer used was prepared using NaCl, CaCl<sub>2</sub>, MgCl<sub>2</sub>, KCl and KH<sub>2</sub>PO<sub>4</sub> from Sigma-Aldrich (Gillingham, UK). Pepsin used was from porcine gastric mucosa (Sigma-Aldrich  
25 Company Ltd., United Kingdom).

## Viscosity Measurements

Cereal bars were cut into pieces. 25g milk and 3g cereal bar particles were added to 15ml  
30 gastric juice. The model stomach system used in this research was set up using a shaking incubator, a magnetic stirring and a beaker. A magnetic stirrer was placed in the 100ml beaker filled with gastric juice (49mM NaCl, 3.6mM CaCl<sub>2</sub>, 1.5mM MgCl<sub>2</sub>, 12mM KCl,

6.4mM KH<sub>2</sub>PO<sub>4</sub>; pepsin; pH 2.5) and the food complex before putting in a shaking incubator. The shaking incubator was set to 37°C and 130rpm in order to simulate the conditions in a human stomach. Each sample was digested for 4 hours. Every 2 hours, samples were taken out to measure viscosity.

5

Viscosity was measured using the Rapid Visco Analyzer (RVA) (Newport Scientific, Australia). Viscosity was measured as a function of constant temperature (25°C) and shear rate (180rpm) for a total period of 14 minutes. Viscosity measurement of each sample was repeated twice.

10

Viscosities of the three types of milk were 88cP for LBG milk with 1.69% casein and 0.32% LBG, which is similar to commercial milk, 170cP for LBG rich milk with 1.41% casein and 0.50% LBG, 200cP for casein rich milk with 4.69% casein and 0.14% LBG.

15 The initial viscosities (viscosities at 0 hour digestion) of combinations of milk and cereal bars in model stomach were around 60cP for LBG milk with 1.69% casein and 0.32% LBG, 80cP for LBG rich milk with 1.41% casein and 0.50% LBG, 80cP for casein rich milk with 4.69% casein and 0.14% LBG.

## 20 **Effect of Milk**

Cereal bar and milk combinations were made as: B1 + XCS: a combination of LBG rich milk (1.69% casein, 0.32% LBG) and cereal bars containing XCS (Xanthan and particulate thickener (cross linked cold water swelling waxy maize starch)); B1+NXCS: a  
25 combination of LBG rich milk (1.69% casein, 0.32% LBG) and cereal bars without XCS; B1(no LBG)+XCS: a combination of milk without LBG (1.69% casein) and cereal bars containing XCS; Water+XCS: a combination of water and cereal bars containing XCS. Values showed were the average of two samples.

30 The results are shown in Fig. 8 and show that when xanthan was removed from the cereal bar there is at least a 4-fold decrease in viscosity. Additionally, when the milk composition was replaced by water a similar decrease was seen. The inclusion of milk protein in water

(but no LBG) shows a 2.5-fold decrease in viscosity, as a result of structure now only being induced by the leaching of xanthan and the gastric structuring of milk protein.

5 Although it was found that the presence of LBG in milk contributed to an increase in viscosity and interacted with xanthan during digestion, how the phase concentration and phase volume ratio of LBG in milk influenced the interactions in a model stomach was unclear. For this reason, the effect of different types of milk on the viscosities of the foods during digestion was investigated.

### 10 **Effects of Milk with varying amounts of protein and polysaccharide**

To evaluate the effects of milk with varying amounts of protein and polysaccharide, four combinations of milk and cereal bars were investigated: a) combination of casein rich milk (4.69% casein, 0.14% LBG; A1) and a cereal bar containing XCS; b) combination of LBG rich milk (1.69% casein, 0.32% LBG; B1) and a cereal bar containing XCS; c) 15 combination of casein rich milk (4.69% casein, 0.14% LBG; A1) and a cereal bar without XCS; d) combination of LBG rich milk (1.69% casein, 0.32% LBG; B1) and a cereal bar without XCS. Cereal bars were made using the above procedure, dispersing XCS in oil first.

20

Fig.9 shows the viscosities of combinations of milk with similar phase concentration and cereal bars in model stomach system, indicating that while the phase volume of the polysaccharide and protein are changing in the 'milk' the increase in viscosity is seen when xanthan is present in the cereal bar (both showing a ~400cp increase in the presence of 25 xanthan)

To evaluate this further, four more combinations of milk and cereal bars were investigated: a) combination of LBG rich milk (1.69% casein, 0.32% LBG; B1) and a cereal bar containing XCS; b) combination of LBG rich milk (1.41% casein, 0.50% LBG; B0) and a 30 cereal bar containing XCS; c) combination of LBG rich milk (1.69% casein, 0.32% LBG; B1) and a cereal bar without XCS; d) combination of LBG rich milk (1.41% casein, 0.50%

LBG; B0) and a cereal bar without XCS. Cereal bars were made with the above procedure, dispersing XCS in oil first.

Fig.10 shows viscosities of combinations of milk with similar phase volume ratio and cereal bars in model stomach system. The increase in LBG concentration (B0) shows an enhancement in viscosity increase when xanthan and a swellable particulate is included in the cereal bar.

### Example 3 Biscuit and Yogurt Drink

10

#### Biscuit Preparation

Ingredient	Source	% in recipe	
		Xanthan & Starch	Control
Balmoral Biscuit Flour	Whitwoth Bros Ltd	16.40	21.83
Rolled Oats	Retail/Morning Foods	3.84	5.10
Biscuit Wholemeal Flour	Whitwoth Bros Ltd	8.78	11.23
Wheat Bran	Whitwoth Bros Ltd or Elf Foods Loughborough	0.46	0.60
Gran sugar	Brake Bros Ltd	6.2	8.28
Demerara Sugar	Brake Bros Ltd	2.56	3.42
Golden Syrup	Brake Bros Ltd	1.4	1.87
Light Malt Extract powder	Muntons PLC	0.44	0.66
Solid Vegetable Fat	Trex, purchased at supermarket [Sainsburys, Asda, Morrisons, Tesco]	10.2	13.69
Vegetable Oil	Sunflour Oil, Morrison PLC or Brake Bros Ltd	4.91	11.71
Water 1		4.22	0.15
Water 2		11.54	9.38
Eaziglaze	Ulrick & Short	11.2	9.37
Skimmed Milk Powder	Brake Bros Ltd	0.85	1.13
Bicarbonate of Soda	Brake Bros Ltd	0.82	1.08
Grindsted Xanthan Clear Supra	Forum Group Ltd	1.48	0.00
Deliquess F (Starch)	Ulrick & Short	14.7	0.00

Gran sugar, Demerara sugar, golden syrup, light malt extract, solid vegetable fat and vegetable oil were mixed together. Water 1 and Eaziglaze were mixed together and then added to fat/sugar mix. All remaining dry ingredients, Balmoral biscuit flour, rolled oats, biscuit wholemeal flour, wheat bran, skimmed milk powder, bicarbonate of soda, Grindsted Xanthan Clear and Deliquess F were added and mixed. Finally water 2 was mixed into the formulation to create dough. The dough was rested for up to 1 hour before rolling, cutting and finally baking at 240°C for 4 minutes, heat was then reduced to 180°C and baked for up to a further 6 minutes. Final biscuit weight was 20g.

10

### Yogurt Drink Preparation

Ingredient	Source	% in recipe	
		LBG	Control
Locust Bean Gum (LBG)	Forum Group Ltd	0.31	0
Water		12.75	0
Fresh Skimmed Milk	Co-operative Food	55.26	64.00
Skimmed Milk Powder (SMP)	Brake Bros Ltd	25.68	29.19
Live Low Fat Natural Yogurt	Retail	5.93	6.73
Arthur Branwell Lemon TEG 10313675	Arthur Branwell	0.04	0.04
Arthur Branwell Lime TEG 10315324	Arthur Branwell	0.04	0.04

LBG and SMP were blended and added to the water and fresh milk. This mixture was heated to 82°C with constant blending. When at 82°C, the Arthur Branwell Lemon TEG 10313675 and Lime TEG 10315324 were added and formulation was cooled to 45°C. When at 45°C, the Live Low Fat Natural Yogurt was mixed in to the formulation and the mixture was poured into containers and incubated at 36°C for up to 24 hours. The yogurt was stirred before decanting into pots and sealed for storage. For control yogurt preparation, the LBG powder and water was omitted.

20

### Simulated gastric juice preparation

Simulated gastric juice was prepared with 1M NaCl purchased from Fisher Scientific Ltd, United Kingdom and 5M HCl purchased from Sigma-Aldrich Company Ltd., United Kingdom and Pepsin (from porcine gastric mucosa (Sigma-Aldrich Company Ltd., United Kingdom)).

### Assessment of parameters in biscuit and yogurt kit

10 In this example, the biscuit and yogurt drink preparations containing varying concentrations of xanthan gum, Deliquess F and LBG were prepared using the above methods however the % in recipe concentrations were adjusted to align with the %w/w<sub>kit</sub> requirements in the table below.

Code	% w/w <sub>kit</sub>			
	Starch	XG	LBG	Protein
A	0	0	0	0
B	2.5	0.2	0.1	6.61
C	2.5	0.2	0.5	6.51
D	2.5	1.6	0.1	6.61
E	2.5	1.6	0.5	6.51
F	2.5	3	0.1	6.61
G	2.5	3	0.5	6.51
H	7.5	0.2	0.1	6.61
I	7.5	0.2	0.5	6.51
J	7.5	1.6	0.1	6.61
K	7.5	1.6	0.5	6.51
L	7.5	3	0.1	6.61
M	15	0.2	0.1	6.61
N	15	0.2	0.5	6.51
O	15	1.6	0.1	6.61
P	15	1.6	0.5	6.51

15

### Viscosity measurements in model stomach system

Biscuits were crushed and mixed with 130g yogurt in a beaker to which 25ml simulated gastric juice was added. Beakers were placed in an oscillating incubator set at 37°C. 20ml

collections were made at 0, 60, 120, 210, and 270 minutes and each transferred into a 50ml falcon tube.

5 Viscosity was measured using the Rapid Visco Analyser (RVA), Newport Scientific, Australia. Viscosity was measured as a function of constant temperature (37°C) and shear rate (180rpm) for a total period of 5 minutes. Data represents the mean of three repeats.

10 Figure 11 shows the range of viscosities when the starch, xanthan gum, locust bean gum and protein concentrations are varied in the example kit. This shows that interactions occur between the four variables at concentrations within the patent constraint. Figure 11 shows that there is a significant increase in viscosity when the concentration of LBG is increased (\*  $p < 0.05$ ).

#### 15 **Example 4 Study**

**Study to assess the tolerability and appetite suppressant effect of a mixed macronutrient gel in healthy volunteers, when consumed as a midmorning snack**

#### 20 **Protocol**

25 Six healthy, normal weight (BMI from 18-25), non-vegetarian men, were recruited from the staff and students of the University via poster advertisement. All subjects attended an initial medical screening visit to confirm their suitability for the study. They were asked to complete a 3 day diet diary (2x week days and 1 weekend day) for baseline macronutrient and energy intake assessment before attending their first study visit. Those who were taking medication or herbal supplements, were restricting their dietary intake to control their weight, or who could not eat the standard foods provided, were excluded from the study.

30 Subjects attended the laboratory for 2 study visits, separated by a week. These visits took place in the morning after subjects had fasted from midnight the night before, and a standard (low fibre) meal, which consisted of a chicken and bacon pasta ready meal, 2x

white bread rolls, sponge pudding and custard, was provided for their evening meal on the day before each visit. On arrival, subjects completed an appetite assessment and answered questions relating to their bowel habits and any adverse gastro-intestinal (GI) symptoms that they had experienced in the previous 24hrs.

5

They were then given a low fibre cereal breakfast (30g Rice Krispies, 125ml semi-skimmed milk; macronutrient composition of meals shown in Table 2). Two and a half hours after eating breakfast (t=150min), subjects were given the test snacks to consume. On one study visit subjects received the 473 / 510 bar and drink, and on the other study visit the 826 / 794 combination were consumed. The order in which subjects consumed the '473' or '826' combination of snacks was randomised at the point of entering the study.

10

They then ate an *ad libitum* pasta-based test meal and were instructed to eat until they felt comfortably full. Subjects remained in the laboratory for the hour following lunch. Subjects could drink water (for thirst) during the study day.

15

At the end of the 310mins, subjects left the laboratory and recorded in a diary any GI symptoms they experienced, and everything they ate and drank over the rest of the day, and the following 24hrs.

20

### **Ingredients and procedure for preparation of foodstuffs**

#### **794 and 510 Milk**

25

Weight all ingredients for correct batch size

<b>Ingredient</b>	<b>Source</b>	<b>% in recipe</b>
RO water	RO water	59.88
Locust Bean Gum [LBG]	Danisco	00.20
Skimmed Milk Powder [SMP]	Brake Bros Wholesale	39.92
Total		100.00

30

Blend SMP & LBG together. Add RO water into the Jam Pan and heat to 80 °C, with vortex from Silverson Blender. Continue vortex with Silverson Blender, add powder mix

[LBG+SMP] slowly until a smooth blend is obtained. Check temperature and increase steam intake to reach / return to minimum temperature of 72 °C for 15 seconds. Discharge into clean vessels (200ml).

### 826 Bar

- 5 Pre- weight all ingredients for correct batch size

<b>Ingredient</b>	<b>Source</b>	<b>% in recipe</b>
Balmoral Biscuit Flour	Whitworth Bros Ltd	30.81
Rolled Oats	Morning Foods via Brake Brother Wholesale	5.00
Biscuit Wholemeal Flour	Whitworth Bros Ltd	13.99
Wheat Bran	Whitworth Bros Ltd	0.60
Cornflour	Brake Brother Wholesale	2.92
Gran sugar	Brake Brother Wholesale	8.11
Demerara Sugar	Brake Brother Wholesale	3.35
Golden Syrup	Brake Brother Wholesale	1.84
Light Malt Extract	Muntons PLC	0.79
Fat	<b>TBC</b>	13.42
Vegetable Oil	Brake Brother Wholesale	5.59
Skimmed Milk Powder	Brake Brother Wholesale	1.11
Bicarbonate of Soda	Brake Brother Wholesale	1.06
Salt	Brake Brother Wholesale	0.46
Water	RO water	5.86
Thixate*	Blended recipe , see table below	5.08

### \*Thixate Mix

<b>Ingredient</b>	<b>Source</b>	<b>% in recipe</b>
Grindsted Xanthan Clear Supra	Danisco DuPont	11.76
Deliquess F	Ulrick & Short	58.82
Vegetable Oil	Brake Brother Wholesale	29.41

10

Line baking trays with silicon parchment and prepare plastic sheeting for pastry brace.

Blend Thixate recipe and set aside covered with other ingredients. Cream all ingredients except flour and Thixate.

15

5 Blend in Thixate. Add flour then mix at min speed for 1 minute, scrape down, and then mix for another 30 seconds. Stand dough for 10 minutes (can leave for up to 1 hour) covered at ambient temperature. Set Deck oven to pre-heat. Set oven temperature to 240°C.

Place dough between sheets of plastic on the Pastry Brace belt and reduce to 6mm, Dock the dough.

Using the XX size pastry cutters cut the dough and place on the lined baking sheets.

10 Bake in oven at 240 °C for 4 minutes, then move to 180 °C for 4 minutes for Control Mix & 6 mins for Thixate mix. Remove from oven and cool on cool trays in the proving oven.

When cooled check weigh (25g) and pack into metal pouches

#### **473 Bar**

As above, minus “Thixate”.

#### 15 **Statistics**

Data were initially checked for normality of distribution using the criteria of  $z$  score between -1.96 and 1.96. Single data points were compared using paired students  $t$ -test, and comparison of dietary energy intake over the recording periods was made using one-way  
20 ANOVA with repeated measures. Relationships were considered significant when  $p < 0.05$ . All data were analysed using SPSS version 16.0 (Statistical Package for the Social Sciences 2000).

25 Data in tables are displayed as the means with the standard deviations shown in parentheses, where applicable. Those data displayed in the figures are the means, with error bars indicating the standard error of the means.

#### **Adverse events**

30 No adverse events were recorded

## Results

Ten individuals were screened for this study, with 6 being recruited. One was declined due to being underweight (BMI <18 kg.m<sup>2</sup>) and 3 were unable to eat the standard meals, on religious grounds. Subject characteristics are shown in the below table.

*Table 1: Subject characteristics*

	Subjects (n=6)
Height (cm)	178 (5.4)
Weight (kg)	71.3 (8.7)
BMI (kg.m <sup>-2</sup> )	22.4 (1.7)
Age (yrs)	23 (5.3)

No subject reported any change in bowel habits (frequency or change in Bristol Stool scale) following either study. When asked whether they felt that their appetite was affected by the products, 5 out of the 6 subjects said 'no', with one saying that the products 'filled me up'.

*Table 2: Composition of the standard meals*

	Standard evening meal	Breakfast	Pasta Meal (per 100g)
Energy (kcal)	1383	168	186
Protein (g)	46.9	5.7	7.0
Fat (g)	47.7	2.3	5.9
Carbohydrate (g)	189	33.3	28.6
Total Sugars (g)	74	8.5	5.4
Fibre (g)	4.8	0.2	1.1

It was observed that suppression of appetite immediately after consumption of 826 was numerically greater than after consumption of 473. Moreover, despite subjective appetite of the group being the same ( $P=1.00$ ) prior to consumption of the *ad libitum* meal, 5 out of the 6 subjects consumed at least 140kcal less (mean 450kcal, range 143 - 896kcal) on the visit where they had been given the 826/794 snack combination, resulting in the group mean being significantly lower on the 826 visit when compared to the 473 day ( $P<0.05$ ; figure 12). The sixth subject consumed the same amount of pasta on both study days (414g vs. 418g).

10

It will be appreciated by those skilled in the art that the foregoing is a description of preferred embodiments of the present invention and that variations in design and construction may be made to the preferred embodiment without departing from the scope and spirit of the invention as defined by the appended claims.

**Claims:**

1. A composition comprising at least about 0.05% w/w of xanthan gum or  $\kappa$ -carrageenan, at least about 2.5 % w/w of swellable particulate and at least about  
5 0.125 % w/w of a protein.
2. The composition according to claim 1 further comprising at least about 0.02 %  
10 w/w a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan.
3. A composition comprising at least about 0.05% w/w of xanthan gum or  $\kappa$ -carrageenan, at least about 2.5 % w/w of swellable particulate, and at least  
15 about 0.02 % w/w of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan.
4. The composition according to claim 3 further comprising at least about 0.125 %  
protein.
5. A composition comprising at least about 0.05% w/w  $\kappa$ -carrageenan and at least  
20 about 2.5 % w/w of swellable particulate.
6. The composition according to claim 5 further comprising at least about 0.125 %  
protein and/or further comprising at least about 0.02 % w/w of a polysaccharide  
25 which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan.
7. The composition according to claims 2 to 6 wherein the polysaccharide is a  
galactomannan or galactomannan, preferably locust bean gum.
8. The composition according to claims 1 to 2 and 4 to 7 wherein the protein is an  
30 edible protein capable of supporting an oil in water emulsion, preferably  
wherein the protein is selected from the group consisting of animal milk

proteins, preferably caseins, and plant milk proteins, preferably, soy, grain, rice, pea and potato.

- 5 9. The composition according to any preceding claim wherein the swellable particulate is swellable at a temperature below about 60°C.
- 10 10. The composition according to any preceding claim wherein the swellable particulate comprises polymer molecules that have been stabilized in the particulate form by either chemical or physical cross-linking.
- 11 11. The composition according to any preceding claim wherein the xanthan gum or  $\kappa$ -carrageenan forms a polymeric solution in water.
- 15 12. The composition according to any preceding claim wherein the swellable particulate comprises one or more of the following modified or unmodified starch, citrus fibre, particulate xanthan gum, fibrous cellulose, oats, swellable gel particles and surfactant micelles.
- 20 13. The composition according to any preceding claim wherein the swellable particulate comprises starch and wherein the starch is derived from potato, maize, tapioca, rice, wheat, cassava, pea or any other suitable material.
- 25 14. The composition according to any preceding claim comprising an additive selected from the group consisting of caffeine, colourings, flavourings, preservatives, vitamins, minerals, amino acids, and mixtures thereof.
- 30 15. A kit for providing an edible gel in the stomach of an individual, said kit comprising separate first and second parts, wherein the first and second parts are different food stuffs, and wherein when the first part and the second part are mixed they can form an edible gel.

16. The kit according to claim 15 wherein the mixing step is performed in the mouth, stomach, or immediately prior to ingestion.
- 5 17. The kit according to claim 15 or 16 wherein the first part is a solid food stuff and the second part is a liquid food stuff.
18. The kit according to claim 15 or 16 wherein both the first part and the second part are solid food stuffs.
- 10 19. The kit according to claim 18 wherein the first part or second part is a coating on the surface of the other part.
20. The kit according to claim 15 or 16 wherein both the first part and the second part are liquid food stuffs.
- 15 21. The kit according to claim 15 or 16 wherein the first part is a liquid food stuff and the second part is a solid food stuff
22. The kit according to claims 15 to 20 wherein the first part comprises xanthan gum or  $\kappa$ -carrageenan, and a swellable particulate.
- 20 23. The kit according to claim 22 wherein the first part comprises at least about 0.05% w/w<sub>kit</sub> of xanthan gum or  $\kappa$ -carrageenan and at least about 2.5 % w/w<sub>kit</sub> of swellable particulate.
- 25 24. The kit according to claims 15 to 23 wherein the second part comprises protein.
25. The kit according to claim 24 wherein the second part comprises at least about 0.125 % w/w<sub>kit</sub> protein.
- 30 26. The kit according to claims 15 to 25 wherein the second part comprises a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan, preferably locust bean gum.

27. The kit according to claim 26 wherein the second part comprises at least about 0.02 % w/w<sub>kit</sub> polysaccharide which forms a synergistic gel with xanthan and/or κ- carrageenan, preferably locust bean gum.
- 5
28. A range of food stuffs comprising a plurality of kits according to claims 15 to 27.
29. A range of food stuffs according to claim 28 wherein the first parts and seconds parts of each of the plurality of kits will form an edible gel with the other of the first parts and second parts of the kits making up the remainder of the of the range.
- 10
30. A range of food stuffs for providing an edible gel in the stomach of an individual, said range comprising a plurality of separate first and second parts, wherein the first and second parts are different food stuffs, and wherein when any one of the first parts is mixed with any one of the second parts they can form an edible gel.
- 15
31. The range according to claim 30 wherein the mixing is performed in the mouth, stomach, or immediately prior to ingestion.
- 20
32. The range according to claim 30 or 31 wherein the first part is a solid food stuff and the second part is a liquid food stuff.
- 25
33. The range according to claim 30 or 31 wherein both the first part and the second part are solid food stuffs.
34. The range according to claim 33 wherein the first part or second part is a coating on the surface of the other part.
- 30

35. The range according to claim 30 or 31 wherein both the first part and the second part are liquid food stuffs.
- 5 36. The range according to claims 30 to 35 wherein the first part comprises xanthan gum or  $\kappa$ -carrageenan, and a swellable particulate.
- 10 37. The range according to claim 35 wherein the first part comprises at least about 0.05% w/w<sub>kit</sub> of xanthan gum or  $\kappa$ -carrageenan and at least about 2.5 % w/w<sub>kit</sub> of swellable particulate.
- 15 38. The range according to claims 30 to 37 wherein the second part comprises protein.
39. The range according to claim 38 wherein the second part comprises at least about 0.125 % w/w<sub>kit</sub> protein.
- 20 40. The range according to claims 30 to 39 wherein the second part comprises a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan, preferably locust bean gum.
- 25 41. The range according to claims 40 wherein the second part comprises at least about 0.02 % w/w<sub>kit</sub> of a polysaccharide which forms a synergistic gel with xanthan and/or  $\kappa$ -carrageenan, preferably locust bean gum.
- 30 42. A method for providing an edible gel in the stomach of an individual comprising the steps of:
- a. providing a first part;
  - b. providing a separate second part;
  - c. mixing the first and second parts; and
  - d. forming a gel from the resulting mixture;
- characterised in that the first part and second part are different food stuffs.

43. The method according to claim 42 wherein the mixing step is performed in the mouth, stomach, or immediately prior to ingestion.
- 5 44. The method according to claim 42 or 43 wherein water is added during the mixing step or subsequent thereto.
45. The method according to claims 42 or 43 wherein the first part is a solid food stuff and the second part is a liquid food stuff.
- 10 46. The method according to claims 42 or 43 wherein both the first part and the second part are solid food stuffs.
47. The method according to claim 46 wherein the first part or second part is a coating on the surface of the other of the first and second part.
- 15 48. The method according to claims 41 or 43 wherein both the first part and the second part are liquid food stuffs.
49. The method according to claims 42 to 48 wherein the first part comprises at  
20 least about 0.05% w/w<sub>kit</sub> of xanthan gum or  $\kappa$ -carrageenan and at least about 2.5 % w/w<sub>kit</sub> of swellable particulate.
50. The method according to claims 42 to 49 wherein the second part comprises at  
25 least about 0.125 % w/w<sub>kit</sub> protein.
51. The method according to claims 42 to 50 wherein the second part comprises at  
least about 0.02 % w/w<sub>kit</sub> locust bean gum.
52. The kit, range or method of any preceding claim wherein the swellable  
30 particulate is swellable at a temperature below about 60°C.

53. The kit, range or method of any preceding claim wherein the swellable particulate comprises polymer molecules that have been stabilized in the particulate form by either chemical or physical cross-linking.
- 5 54. The kit, range or method of any preceding claim wherein the xanthan gum or  $\kappa$ -carrageenan forms a polymeric solution in water.
55. The kit, range or method of any preceding claim wherein the swellable particulate comprises one or more of the following modified or unmodified starch, citrus fibre, particulate xanthan gum, fibrous cellulose, oats, swellable gel particles and surfactant micelles.
- 10
56. The kit, range or method of any preceding claim wherein the swellable particulate comprises starch and wherein the starch is derived from potato, maize, tapioca, rice, wheat, cassava, pea or any other suitable material.
- 15
57. The kit, range or method of any preceding claim wherein the protein is casein.
58. The kit, range or method of any preceding claim wherein foodstuffs comprise an additive selected from the group consisting of caffeine, colourings, flavourings, preservatives, vitamins, minerals, amino acids, and mixtures thereof.
- 20
59. The kit, range or method of any preceding claim wherein the viscosity of the edible gel increases upon dilution, preferably in water.
- 25
60. An edible gel formed from the composition, kit, range or using the method of any preceding claim.
61. A nutraceutical or pharmaceutical composition for the treatment of obesity comprising the composition of claims 1 to 14.
- 30

62. A nutraceutical or pharmaceutical kit for the treatment of obesity comprising the kit of claims 15 to 27 or 52 to 59.

5 63. The composition, kit, range or edible gel of any preceding claim or edible gel formed using the method of any preceding claim for use in the treatment of obesity.

10 64. The use of the composition, kit, range or edible gel of any preceding claim or edible gel formed using the method of any preceding claim to treat obesity.

65. The use according to claims 63 or 64 wherein the composition, kit, range, edible gel or edible gel formed using the method of any preceding claim is used at least once per day, preferably one to five times per day, most preferably three times per day, preferably at every meal.

Figures

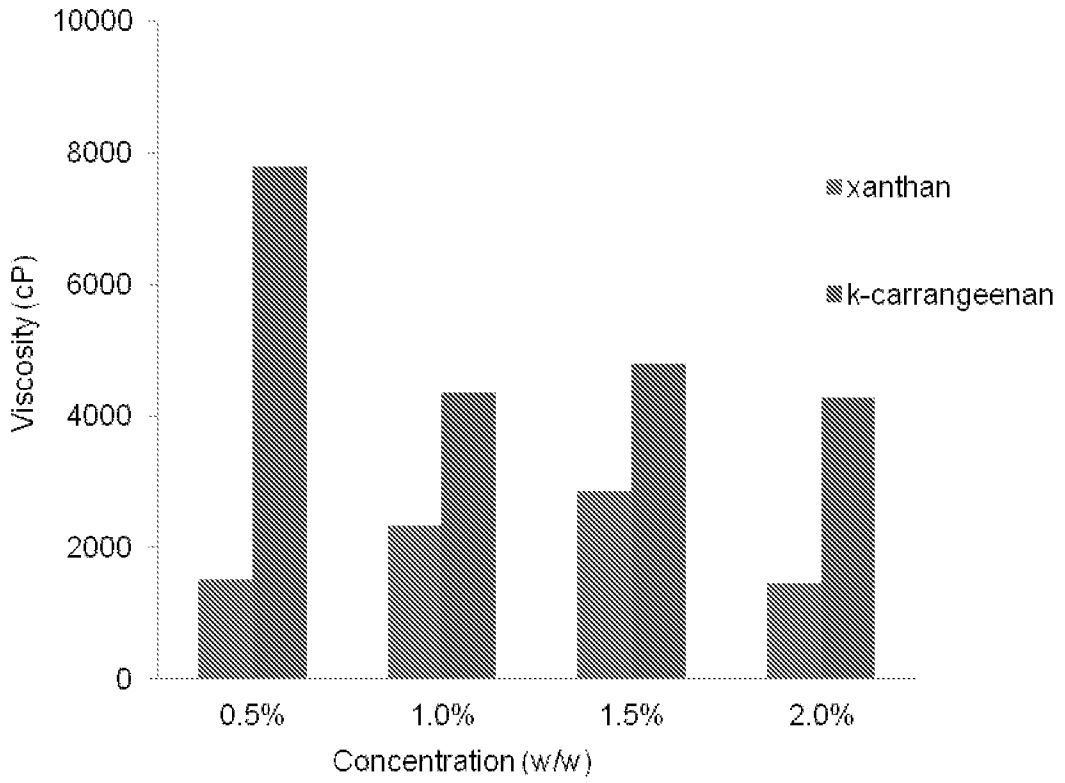


Fig. 1

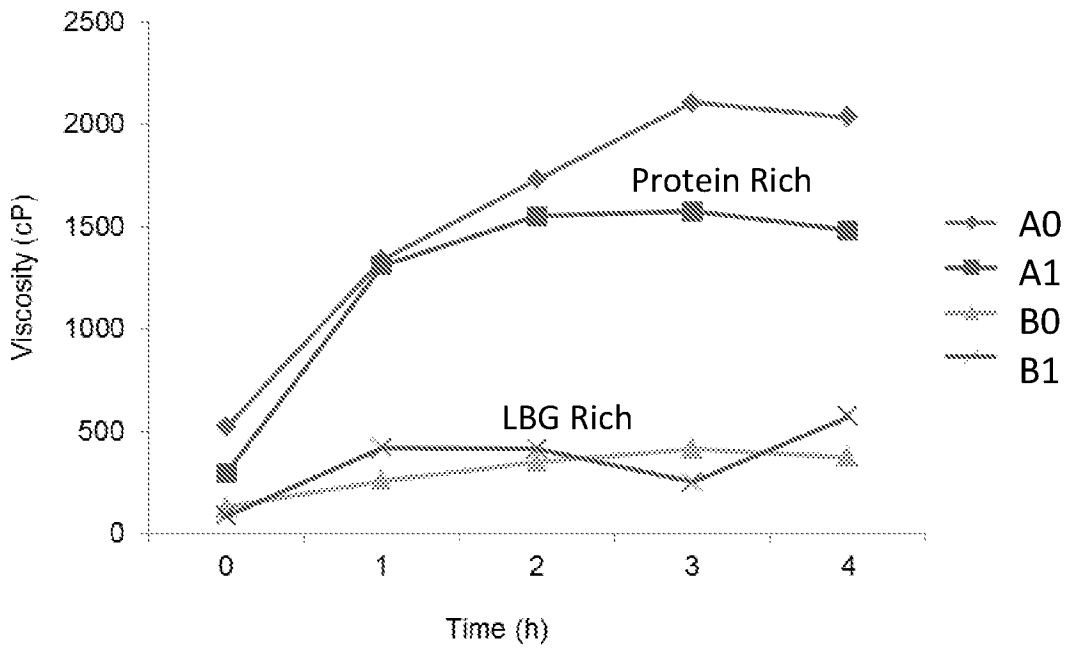


Fig. 2

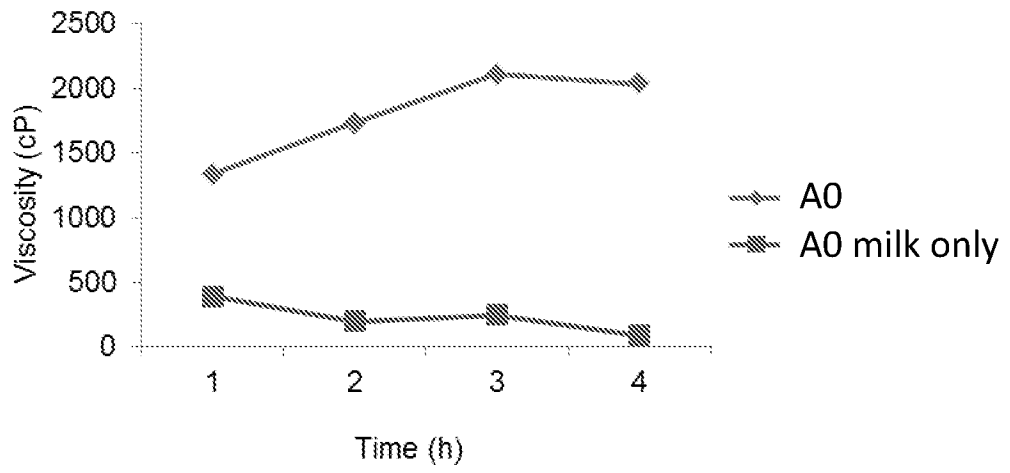


Fig. 3a

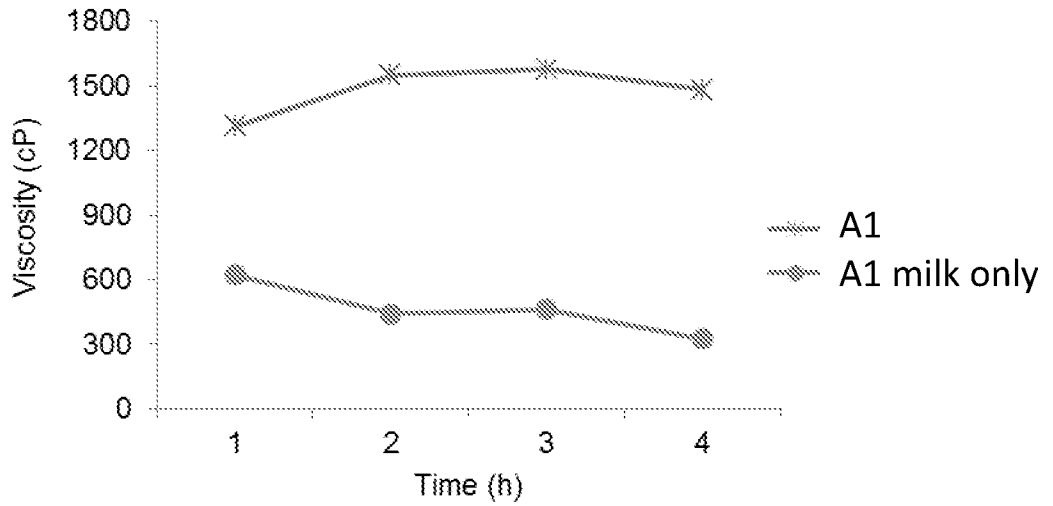


Fig. 3b

3/10

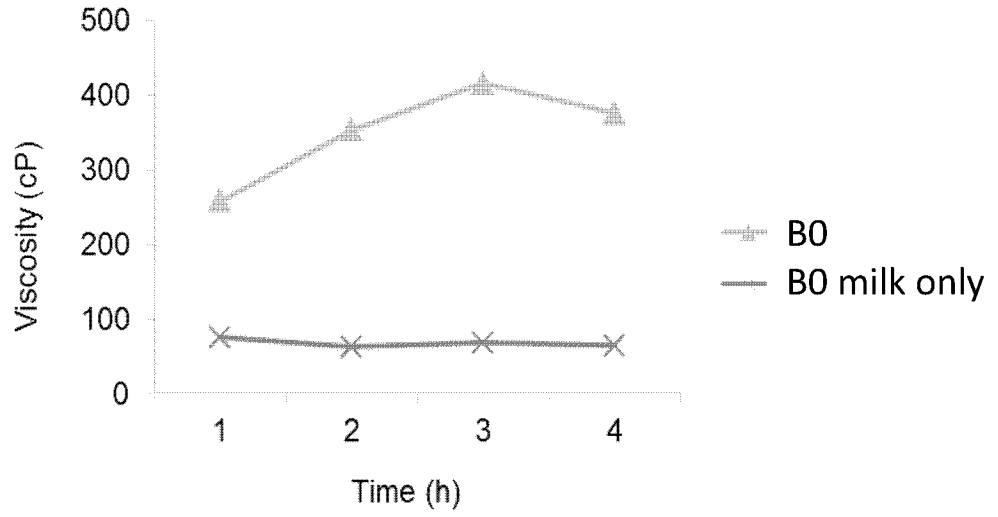


Fig. 3c

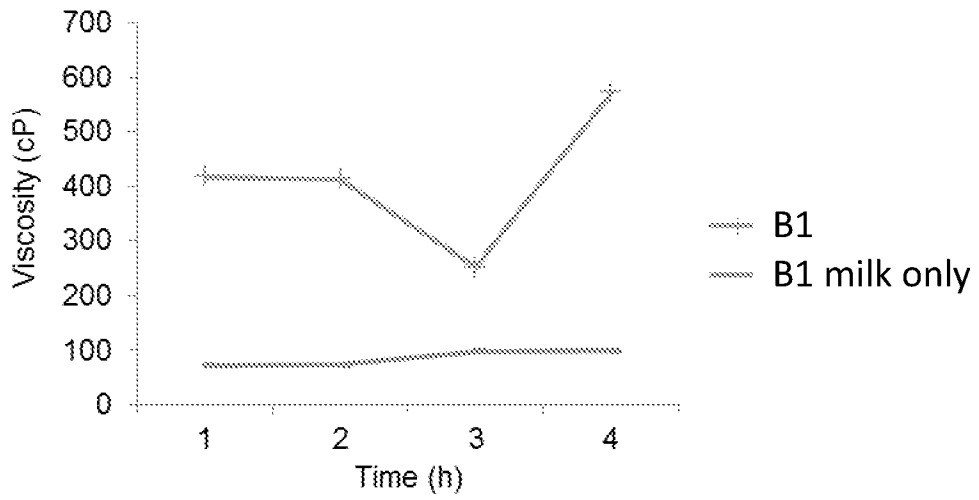


Fig. 3d

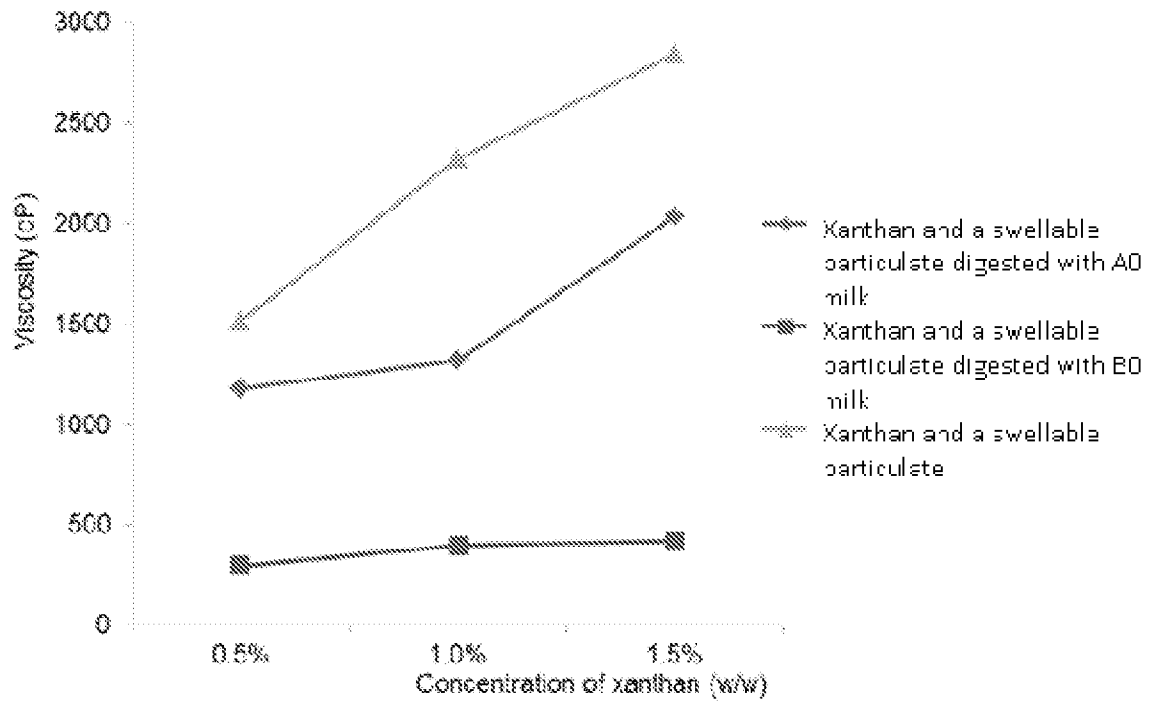


Fig. 4

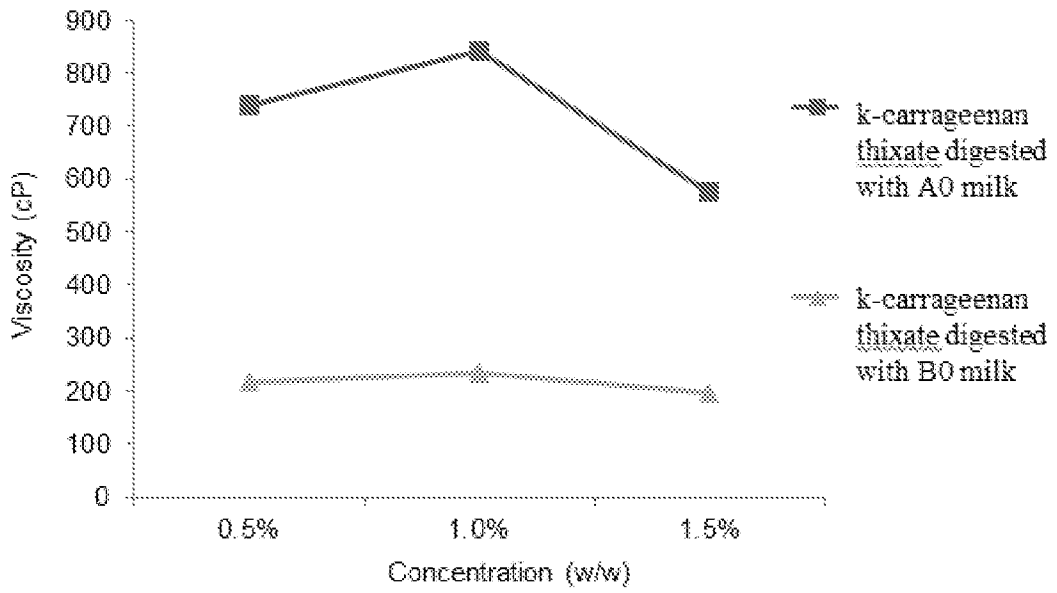


Fig. 5

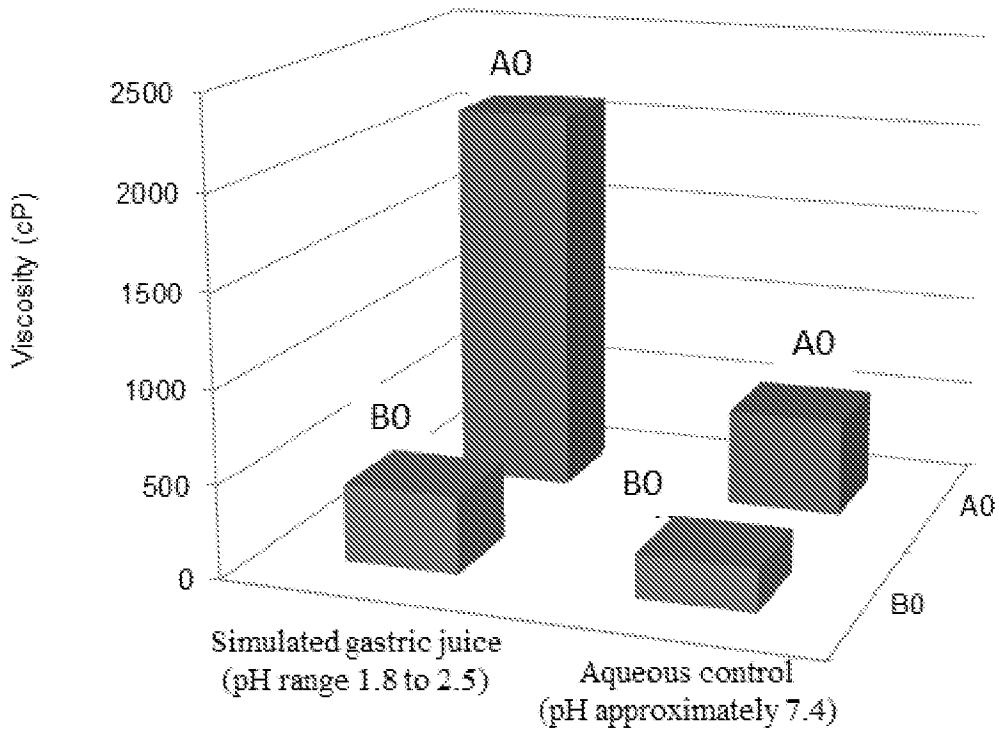


Fig. 6

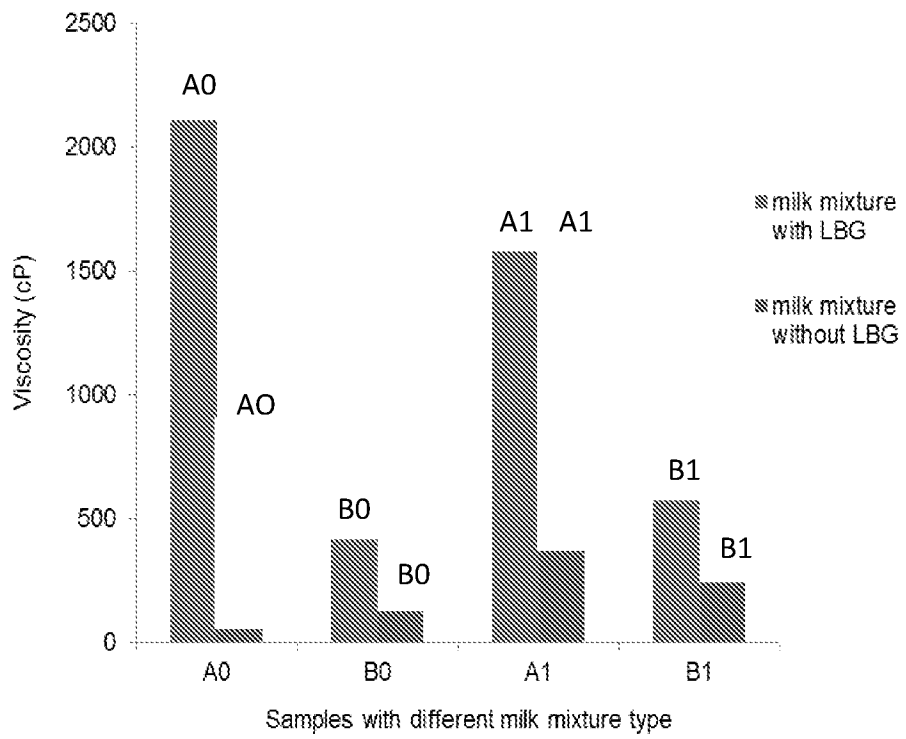


Fig. 7

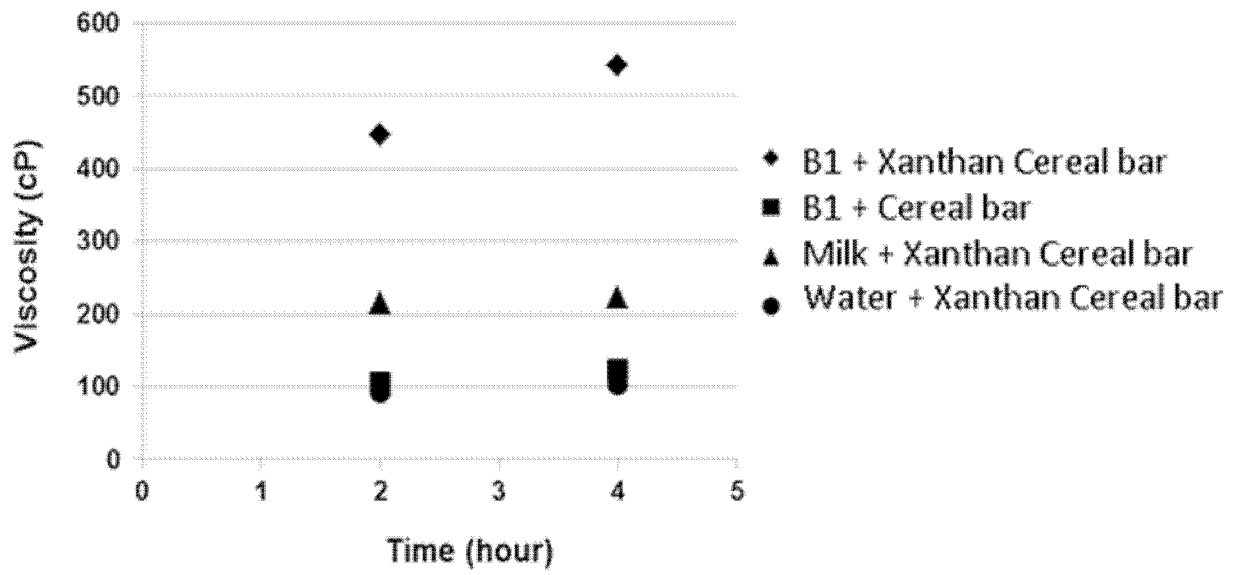


Fig. 8

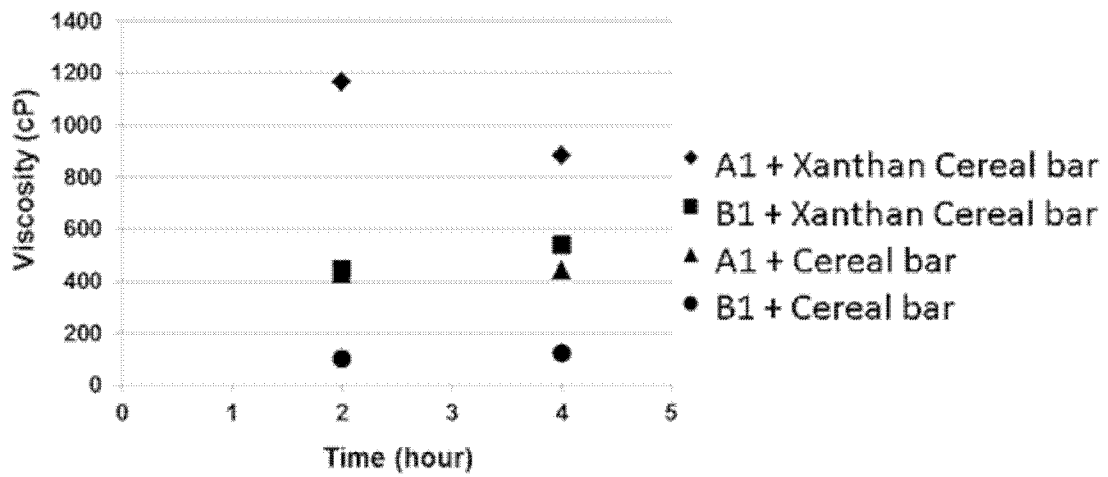


Fig. 9

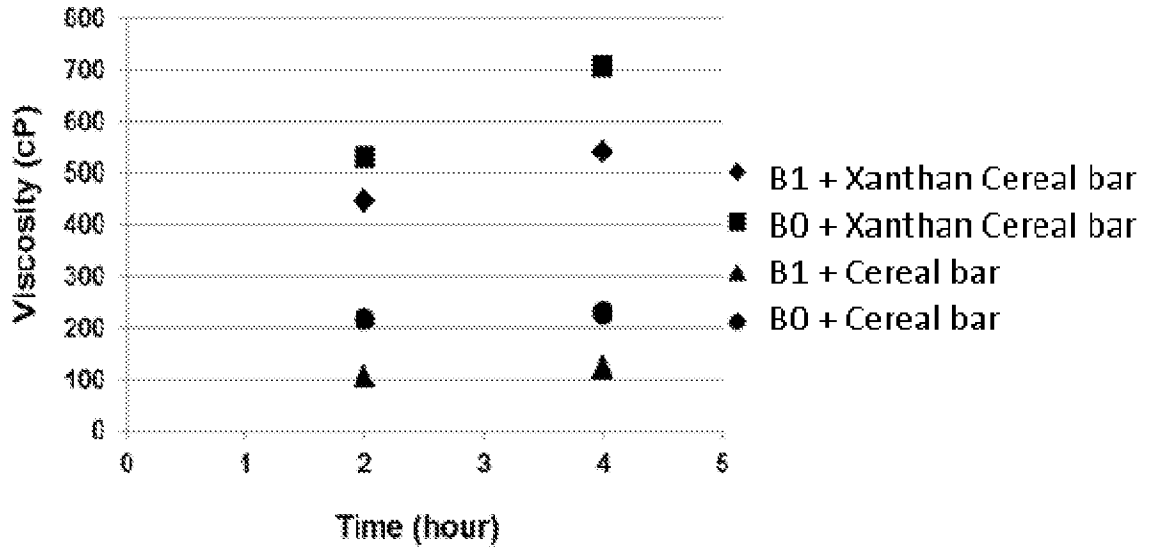


Fig. 10

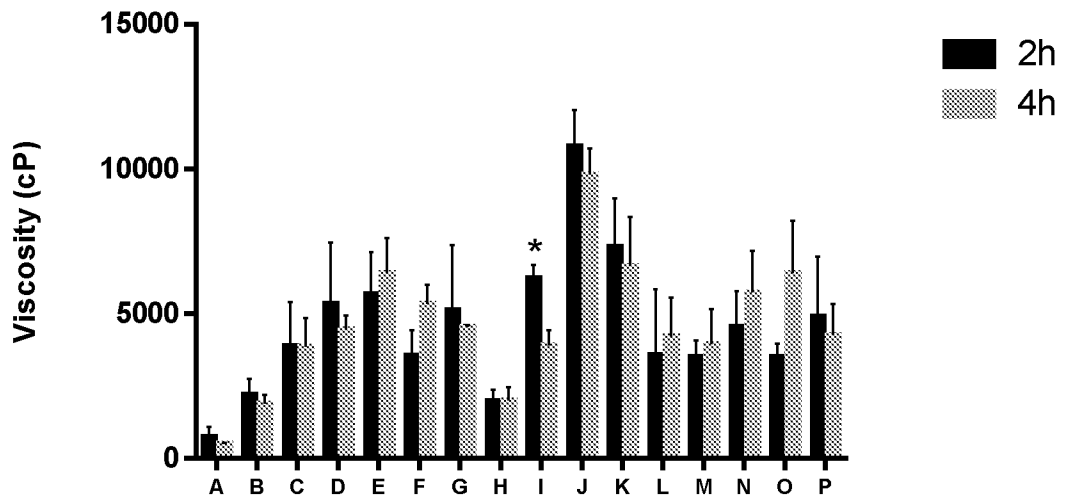


Fig. 11

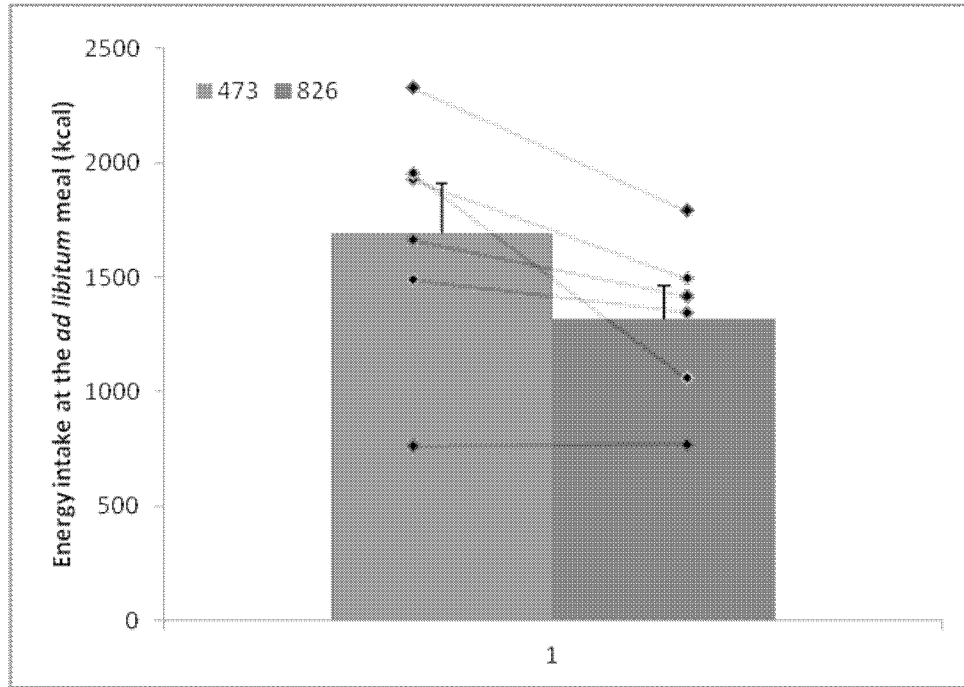


Fig. 12