We have now surprisingly found that it is possible to formulate a solid formulation for oral administration as a solid comprising a non-laxative, relatively low (less than about 6g PEG per day) dose of PEG which is suitable for chronic consumption by healthy subjects.

Thus, in a first aspect, the present invention refers to a solid formulation for oral administration as a solid, comprising: (a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and (b) 10 – 40 % w/w of a solid selected from the group; sorbitol, lactose, dextrates, cellulose, xylitol, maltitol, mannitol.

Thus, in a second aspect, the present invention refers to the use of a solid formulation of the present invention in the manufacture of a medicament for prevention of gastrointestinal disorders or maintaining gastrointestinal health.

Thus, in a third aspect, the present invention refers to a chewable or suckable solid formulation for oral administration as a solid comprising: (a) 2.0 to 3.5g PEG (for example 2.1 to 2.5g) having an average molecular weight of 3000 to 4000 Da; (b) 250 to 500mg (for example 420 to 450mg) of a solid selected from the group: sorbitol, lactose, dextrates, cellulose, xylitol, maltitol, mannitol.

Thus, in a fourth aspect, the present invention refers to a pack comprising a plurality of units of solid formulations according to the present invention.

Accordingly, the present disclosure~~invention~~ provides a solid formulation for oral administration as a solid, comprising:

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 10 – 40 % w/w of a solid.

The disclosure~~invention~~ provides a solid formulation for oral administration as a solid, comprising:

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da;

(b) 10 – 40 % w/w of a solid (sometimes referred to herein as "solid of component (b)"); and optionally

(c) q.s. to 100% w/w of further excipients such as flavourings, sweeteners and lubricants.

Herein, "% w/w" of a component is understood to mean the proportion, as a percentage, that the weight of the respective component makes up of the total weight of the solid formulation.

The present disclosure~~invention~~ further provides a solid formulation for oral administration as a solid, comprising:

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 10 – 40 % w/w of a solid selected from the group; sorbitol, lactose, *dextrates, cellulose, xylitol, maltitol, mannitol.*

The present disclosure~~invention~~ further provides a solid formulation for oral administration as a solid, comprising:

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 10 – 40 % w/w of a solid selected from the group: sorbitol, lactose, lactose and starch (e.g. a compound comprising lactose monohydrate and maize starch such as Starlac®), dextrates, cellulose (such as microcrystalline cellulose), xylitol, maltitol and mannitol.

Preferably, the solid of component (b) is greater than 10% w/w, preferably greater than 12% w/w, more preferably greater than 15% (e.g. 15% to 17%) of the solid formulation. Preferably the weight ratio of component (a) to component (b) is 1.25:1 to 9:1, preferably 2:1 to 7:1, preferably 4:1 to 6:1. In preferred example~~embodiments~~, the ratio of component (a) to component (b) is approximately 5:1.

Preferably, the solid formulation is chewable and/or suckable. It may be a solid tablet, for example a chewable and/or suckable tablet.

It has surprisingly been found that a solid formulation of the invention is pleasantly chewable or suckable, has good taste, structural integrity and beneficial manufacturing properties. By "chewable" or "suckable" is meant herein that the solid formulation is for oral administration and is capable of being chewed or sucked in the mouth so that the first step in the digestive process starts in the buccal cavity. The formulations disclosed herein~~of the present invention~~ are generally not intended to be swallowed whole without first being broken down, at least to some extent, in the buccal cavity prior to consumption. Herein, a powder formulation is not considered suitable for administration as a solid; especially those that require prior solution or suspension in a liquid (for example water) or delivery in an alternative medium or container. A formulation disclosed herein~~of the invention~~ is preferably not effervescent in contact with water.

Formulations of the disclosure~~invention~~ are preferably substantially free from electrolytes. Formulations of the disclosure~~invention~~ that are substantially free from electrolytes may be particularly beneficial for those subjects who are healthy (that is, for present purposes,

have normal bowel movement) but are hypertensive or otherwise following a low sodium diet. For example, they are preferably substantially free from sodium chloride, potassium chloride and sodium bicarbonate. They are preferably substantially free from sulphates or phosphates, for example, they are particularly preferred to be substantially free from sodium sulphate. Formulations described hereinof the invention are preferably substantially free from carbonates, bicarbonates, alkali metal ions and halide ions. Formulations described hereinof the present invention are most preferably substantially free from sodium, potassium, chloride, bicarbonate, carbonate and/or sulphate ions. In many instances, flavourings, lubricants and sweeteners may contain small amounts of electrolytes. Such amounts are not considered herein to be "substantial". Formulations described hereinof the invention are preferably substantially free from alginates and/or ascorbates and/or citrates. By "substantially free from" herein is also meant that the ingredient is not added to the formulation during preparation or manufacture.

In some examplembodiments, formulations disclosed hereinof the present invention are substantially free from any osmotic agent other than PEG.

The polyethylene glycol (PEG) for use in solid formulations of the disclosureinvention preferably has an average molecular weight (for example a weight average molecular weight), in Daltons, within the range 2,000 to 10,000, preferably 2,500 to 8,500, preferably 3,000 to 8,000, more preferably 3,000 to 6,000, more preferably 2,500 to 6,500, more preferably 2,500 to 4,500 for example 3,000 to 4,500, for example 3,000 to 4,100, for example 3,000 to 4,000. The PEG may have an average molecular weight within the range 6,000 to 10,000, for example 7,000 to 9,000. For example, the PEG may be, or comprise PEG 3,350, PEG 4,000 or PEG 8,000 as defined in national or regional pharmacopoeias. Further examples of suitable PEGs recognized in some national pharmacopoeias include Macrogols, for example Macrogol 4,000. Optionally, the PEG used in formulations of the disclosureinvention may comprise two or more different PEG components. Optionally, the PEG used in formulations may have at least two differing average molecular weights. PEG of the relevant molecular weights in a form suitable for use in humans is available commercially.

In a preferred example~~embodiment~~, PEG is present in the solid formulation in an amount of 60 to 90% w/w, preferably 70 to 90% w/w, more preferably 70 to 89 % w/w, for example 75 to 89 % w/w. In a further example~~embodiment~~, PEG is present in an amount of 78 to 89 % w/w, for example 80 to 85% w/w, for example 81 to 85 % w/w, for example 80 to 84 % w/w, for example 82 to 84 % w/w. In a further example~~embodiment~~, PEG is present in an amount of 50 to 80% w/w, for example 60 to 80% w/w, for example 70 to 80 % w/w, for example 70 to 79% w/w, for example 75 to 79% w/w.

The solid of component (b) of the disclosure~~invention~~ is preferably selected from the group consisting of sorbitol, lactose, lactose and starch, dextrates, cellulose (e.g. microcrystalline cellulose), xylitol, maltitol, mannitol. Lactose or similar ingredients may be present in hydrated form.

Where the solid of component (b) is lactose and starch, the lactose component may be in the form of a monohydrate. The starch component may be derived from any suitable source such as wheat starch, maize starch, potato starch and rice starch. The lactose component may make up 50% to 95% of the lactose/starch solid, for example 60% to 90%, e.g. 70 to 85% such as 85%.

Solids of component (b) of the disclosure~~invention~~ for use in the present invention are preferably of a purity and grade suitable for consumption by e.g. humans.

The solid of component (b) makes up 10 to 40 % w/w of the solid formulation of the invention. In a preferred example~~embodiment~~, the solid of component (b) makes up 10 to 30% w/w of the solid formulation, preferably greater than 10% w/w up to (and including) 30%w/w. For example, the solid of component (b) makes up 10 to 25% w/w, for example 10 to 20% w/w, preferably 12 to 20 % w/w, more preferably 12 to 19% w/w, 12 to 18% w/w, or 12 to 17 % w/w. For example, the solid of component (b) may make up 14 to 20% w/w, 14 to 19% w/w or 14 to 18% w/w 14 to 17% w/w of the solid

formulation of the invention such as 15 to 16.5%w/w of the solid formulation of the invention.

Preferably, the solid of component (b) is mannitol. It has been found by the present inventors that a solid formulation comprising PEG and mannitol is more palatable than a solid formulation comprising PEG and no mannitol, even if flavouring is added. In particular, it has been found that a tablet comprising PEG and mannitol has a much lower requirement for lubricant or lubrication during tablet manufacture than a tablet comprising PEG but no mannitol. A high level of a lubricant in a tablet generally makes the tablet have an unacceptable taste. The reduced level (or absence of) a lubricant as compared with a tablet comprising PEG but no mannitol brings about an improved palatability (taste and mouthfeel) of a chewable or suckable tablet comprising PEG and mannitol.

Typically, solid formulations of dry ingredients are manufactured using dry granulation followed by punching with punch and die equipment. In a punch and die machine, dry ingredients are compressed together. It has surprisingly been found that a solid formulation of the disclosure~~invention~~ comprising PEG and mannitol in the specified proportions has better structural integrity and is more convenient to manufacture than a solid formulation comprising PEG and no mannitol, or a smaller proportion of mannitol. Solid formulations of the disclosure~~invention~~ are less susceptible to capping and laminating during punch and die manufacture than solid formulations comprising a smaller proportion of mannitol, or no mannitol. Solid formulations that become capped or laminated during die pressing are not suitable for use and they become waste. It has been found by the current inventors that a solid formulation containing between 50 and 90% w/w PEG and 10 to 40% w/w mannitol has better tablet pressing characteristics than a solid formulation containing no mannitol or 10%w/w or less mannitol, for example less than 10% mannitol.

Mannitol makes up 10 to 40 % w/w of the solid formulation of the disclosure~~invention~~. In a preferred embodiment, mannitol makes up 10 to 30% w/w of the solid formulation. For example, mannitol makes up 10 to 25% w/w, for example 10 to 20% w/w, preferably 12

to 20 % w/w, more preferably 12 to 19% w/w, 12 to 18% w/w, or 12 to 17 % w/w. For example, mannitol may make up 14 to 20% w/w, 14 to 19% w/w or 14 to 18% w/w 14 to 17% w/w of the solid formulation of the disclosure~~invention~~. Mannitol may be provided in various physical forms. For example, mannitol is available commercially in granular, powder or spray-dried form. In a preferred example~~embodiment~~, the mannitol is granular. Mannitol is commercially available from several suppliers, including Merck, SPI Polyols Inc and Roquette.

In an example~~embodiment~~, the PEG and mannitol are present in a weight ratio of PEG:mannitol of 1.25:1 to 9:1 (e.g. 3:1 to 9:1, or 4:1 to 9:1), preferably 2:1 to 7:1, preferably 4:1 to 6:1 or 4:1 to 8:1, for example 5:1 to 6:1. In preferred example~~embodiments~~ the ratio of PEG to mannitol 5:1 or thereabout.

The structural integrity of the solid formulation is retained when the mannitol is granular mannitol. It is surprising that the solid formulation of the disclosure~~invention~~ is so structurally sound with granular mannitol. In general it is found that granular mannitol cannot be used with concentrations of other materials exceeding 25% by weight (Handbook of Pharmaceutical Excipients, 5th Ed., Pharmaceutical Press, 2006, page 452). The current inventors have found that the solid formulations of the disclosure~~invention~~, which comprise 60 to 90% w/w of materials other than mannitol, are readily manufacturable and have good structural integrity.

It has also surprisingly been found that a solid formulation of the disclosure~~invention~~ comprising PEG and mannitol in the specified proportions is less prone to sticking to punch and die equipment than a solid formulation comprising PEG and a smaller proportion of mannitol, or no mannitol. This is particularly important when manufacturing formulations of the disclosure~~present invention~~ at commercial scale since fouling of the manufacturing machinery may lead to manufacturing down-time with the increased costs associated therewith.

Lubricants can be included in tablet formulations to reduce the propensity for them to stick to the punch or die after die pressing. Examples of lubricants include magnesium stearate, potassium stearate, talc, stearic acid, sodium lauryl sulphate, and paraffin. Mixtures of different lubricants may be used. It has been found that a solid formulation of the disclosure~~invention~~ comprising PEG and mannitol in the specified proportions requires a smaller proportion of lubricant to satisfactorily avoid sticking than a tablet comprising PEG and a smaller proportion of mannitol, or no mannitol. Preferably, a solid formulation of the disclosure~~invention~~ comprises lubricant in an amount of 2.0% w/w or less, for example 1.5% w/w or less, or 1.0% w/w or less. For example it may comprise lubricant in an amount of 0.1 to 0.9% w/w, for example 0.2 to 0.8% w/w, preferably 0.3 to 0.7% w/w. For example, the lubricant is present in ratio of solid of component (b) (such as mannitol): lubricant ratio of 170:1 to 16:1, for example 57:1 to 20:1. A particularly preferred lubricant is magnesium stearate. If the lubricant is magnesium stearate, it is effective to satisfactorily avoid sticking when used at a level of under 1% w/w. Accordingly, in an example~~embodiment~~, the tablet of the invention further comprises magnesium stearate in an amount of 0.1 to 0.9% w/w, for example 0.2 to 0.8% w/w, preferably 0.3 to 0.7% w/w, more preferably 0.5% w/w. It is surprising that magnesium stearate is effective at these levels as, in general, magnesium stearate is required at a level of over 1% in formulations comprising mannitol (Handbook of Pharmaceutical Excipients, 5th Ed., Pharmaceutical Press, 2006, page 452).

Thus the present disclosure~~invention~~ provides a solid formulation for administration as a solid comprising;

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da;

(b) 10 – 40 % w/w of mannitol; and

(c) 0.1 to 0.9% (e.g. 0.2 to 0.8%, 0.3 to 0.7% such as 0.5%) w/w of a lubricant such as magnesium stearate.

In some examplembodiments, the ratio of mannitol:lubricant is preferably 10:1 or greater, preferably, 20:1 or greater e.g. 25:1 or greater such as 30:1 or greater (e.g. 30:1 to 35:1 such as 30.6:1 or 32.4:1).

In an examplembodiment, a solid formulation of the invention does not include any added flavouring. In a preferred examplembodiment, a solid formulation of the invention includes at least one flavouring. Suitable flavourings are available from various flavour manufacturers and suppliers, for example International Flavours and Fragrances Inc. (Duddery Hill, Haverhill, Suffolk, CB9 8LG, United Kingdom), Ungerer & Company (Sealand Road, Chester, CH1 4LP, United Kingdom), Firmenich (Firmenich UK Ltd., Hayes Road, Southall, Middlesex, UB2 5NN, United Kingdom) or S. Black Ltd (Foxholes Business Park, John Tate Road, Hertford, Herts, SG13 7YH, United Kingdom). Examples of suitable flavours include orange, lemon-lime, lemon, citrus, chocolate, tropical fruit, aloe vera, peppermint, tea, strawberry, grapefruit, blackcurrant, pineapple and vanilla, raspberry-lemon, cola flavour, and combinations thereof.

Preferred flavours are peppermint and raspberry-lemon flavour.

A flavouring may be integral in a solid formulation, or it may be coated onto its surface. In one examplembodiment, the flavouring is integral in the solid formulation. In such a solid formulation, the flavouring preferably makes up 0.1 to 15% w/w of the solid formulation. For example, the flavouring may make up 0.1 to 5% w/w of the solid formulation, for example 0.1 to 2.0% w/w, for example 0.2 to 2.0% w/w. When the flavouring is peppermint, it is preferably present at a level of 0.1 to 1.0% w/w, for example 0.15 to 0.5% w/w. This level is particularly preferred when the solid of component (b) such as mannitol is present at a level of 14 to 17 % w/w of the solid formulation of the disclosureinvention. When the flavouring is raspberry-lemon, it is preferably present at a level of 0.5 to 2.0% w/w, for example 1.0 to 2.0%, for example 1.2 to 1.8% w/w. This level is particularly preferred when the solid of component (b) such as mannitol is present at a level of 14 to 17% w/w of the solid formulation of the disclosureinvention.

In an examplembodiment, the solid of component (b) such as mannitol and flavouring are, for example, present in a ratio of solid : flavouring of 170:1 to 3:1; when the flavouring is peppermint, the solid of component (b) such as mannitol and flavouring are preferably present in a ratio of solid : flavouring of 113:1 to 28:1. When the flavouring is raspberry-lemon, the solid of component (b) such as mannitol and flavouring are preferably present in a ratio of solid of component (b): flavouring of 14:1 to 7:1.

A solid formulation of the disclosureinvention may comprise one or more sweeteners. Sweeteners may be sugar-based. Preferably, they are not sugar-based. Preferred sweeteners include aspartame, acesulfame potassium (acesulfame K), sucralose and saccharine or combinations thereof. Alternatively, it can be preferred for formulations of the disclosureinvention to be substantially free from added sweeteners, for example to minimize the number of different components in the formulations. When present, sweeteners may, for example, be present in an amount of 0.01 to 1 % w/w. More preferably, a sweetener may be present in an amount of 0.1 to 1% w/w. The level of sweetener required to obtain a satisfactory taste may depend on the presence, and identity and quantity, of the other components of the formulation.

In general it is not necessary for a solid formulation of the disclosureinvention to include preservatives or anti-oxidants. Nevertheless, low levels of anti-oxidants or preservatives may be included if required. It is preferred that formulations of the present disclosureinvention are also substantially free from "salt taste" masking agents, such as agents that mask the taste of sodium sulphate, (other than flavourings mentioned herein) and from salts of non-fatty acids such as salts of mineral acids.

A solid formulation of the disclosureinvention can be of any convenient size. As mentioned above, a tablet should be sufficiently large to provide the desired quantity of PEG to the subject, but not be so large as to be uncomfortable in the mouth, difficult to chew or suck, or difficult to package. A tablet may, for example have a mass of 0.5 to 10g, more preferably 0.5 to 5g, for example 1.0 to 5.0g, for example 2.0 to 3.5g, for example 2.5 to 3.5g. In one examplembodiment, a tablet of the disclosureinvention has a mass of from 2.5 to 3.0g, for

example 2.75g. For certain uses, where a larger amount of PEG is to be delivered to the subject, a larger tablet may be convenient, for example having a mass of 3 to 10g, for example 3 to 5g, 3 to 7g, 4 to 7g, or 5 to 8g, for example 4 to 7g. For certain uses, where a smaller amount of PEG is to be delivered to the subject, for example for paediatric uses, a smaller tablet may be convenient, for example having a mass of 0.5 to 2.0g, for example 1.0 to 1.75g, for example 1.25 to 1.50g.

A solid formulation of the disclosure~~invention~~ may therefore be a solid formulation of mass 2.0 to 3.5g comprising:

(a) 1.00 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 0.20 – 1.40g of solid such as mannitol.

A solid formulation of the disclosure~~invention~~ may therefore be a solid formulation of mass 2.5 to 3.5g comprising:

(a) 1.25 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 0.25 – 1.40g of solid such as mannitol.

Similarly, a formulation of the disclosure~~invention~~ may therefore be a solid formulation of mass 1.0 to 1.75g comprising:

(a) 0.50 – 1.575g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 0.10 – 0.70g of solid such as mannitol;

As mentioned above, a lubricant (for example magnesium stearate) may be present in a solid formulation of the disclosure~~invention~~ in an amount of 2% w/w or less, for example 1% w/w or less. A solid formulation of the invention of mass 2.0 to 3.5g may therefore comprise 0.07g or less of lubricant, for example 0.35g or less of lubricant. For example, it may comprise lubricant in an amount of 0.002 to 0.0315g, for example 0.004 to 0.028g, for example 0.006 to 0.0245g. A larger formulation of the disclosure~~invention~~ of mass 3.0 to 7.0g may

comprise 0.14g or less of lubricant, for example 0.07g or less of lubricant. For example, it may comprise lubricant in an amount of 0.003 to 0.063g, for example 0.006 to 0.056g, for example 0.009 to 0.049g. A smaller formulation of the disclosure~~invention~~ of mass 1.0 to 1.75g may comprise 0.035g or less of lubricant, for example 0.0175g or less of lubricant. For example, it may comprise lubricant in an amount of 0.001 to 0.01575g, for example 0.002 to 0.014g, for example 0.003 to 0.01225g.

As mentioned above, flavouring may be present in a solid formulation of the disclosure~~invention~~ and, when present, it preferably makes up 0.1 to 15% w/w of the solid formulation. A solid formulation of the disclosure~~invention~~ of mass 2.0 to 3.5g may therefore comprise 0.002 to 0.525g of flavouring, for example 0.002 to 0.175g, for example 0.002 to 0.07g, for example 0.004 to 0.07g of flavouring. A larger formulation of the disclosure~~invention~~ of mass 3.0 to 7.0g may comprise 0.003 to 1.05g of flavouring, for example 0.003 to 0.35g, for example 0.003 to 0.14g, for example 0.006 to 0.14g of flavouring. A smaller formulation of the disclosure~~invention~~ of mass 1.0 to 1.75g may comprise 0.001 to 0.2625g of flavouring, for example 0.001 to 0.0525g for example 0.001 to 0.021g, for example 0.002 to 0.021g of flavouring.

For example, a solid formulation of the disclosure~~invention~~ may comprise:

(a) 50 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da;

(b) 10 – 30 % w/w of solid such as mannitol;

(c) 0.1 – 2.0 % w/w lubricant; and

(d) 0.1 – 15 % w/w flavouring.

In one example~~mbodiment~~, a solid formulation of the disclosure~~invention~~ comprises:

(a) 70 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 3,000 to 8,000 Da;

(b) 10 – 25 % w/w of solid such as mannitol;

(c) 0.1 – 1.5 % w/w magnesium stearate; and

(d) 0.1 – 2.0 % w/w flavouring.

For example, a solid formulation of the disclosure~~invention~~ comprises:

(a) 75 – 89 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 3,000 to 4,000 Da;

(b) 10 – 20 % w/w of solid such as mannitol;

(c) 0.2 – 0.8 % w/w magnesium stearate; and

(d) 0.1 – 1.0 % w/w flavouring.

For example, a solid formulation of the disclosure~~invention~~ may comprise:

(a) 1.00 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da;

(b) 0.20 – 1.40g of solid such as mannitol;

(c) 0.002 – 0.07g lubricant; and

(d) 0.002 – 0.525g flavouring.

In one example~~embodiment~~, a solid formulation of the disclosure~~invention~~ comprises:

(a) 1.40 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 3,000 to 8,000 Da;

(b) 0.20 – 0.875g of solid such as mannitol;

(c) 0.002 – 0.0525g magnesium stearate; and

(d) 0.002 – 0.07g flavouring.

For example, a solid formulation of the disclosure~~invention~~ comprises:

(a) 1.5 – 3.115g polyethylene glycol (PEG) having an average molecular weight within the range 3,000 to 4,000 Da;

(b) 0.20 – 0.70g of solid such as mannitol;

(c) 0.004 – 0.016g magnesium stearate; and

(d) 0.002 – 0.035g flavouring.

For example, a solid formulation of the disclosure~~invention~~ comprises:

(a) 2273 to 2284mg polyethylene glycol (PEG) having an average molecular weight within the range 3,000 to 4,000 Da;

(b) 420 to 446mg of solid such as mannitol;

(c) 13.5 to 13.75mg magnesium stearate; and

(d) 11 to 42mg of flavouring such as peppermint or raspberry/lemon flavouring.

The solid formulations of the disclosure~~invention~~ may be packaged in any convenient fashion. For example a plurality of units (e.g. tablets) of the solid formulation of the present disclosure~~invention~~ (such as 5, 10, 15 or 20) may be packaged in a way conventional in the vitamin supplements industry. For example, they may be packed in a tube (such as a PTFE tube) equipped with a removable and replaceable closing means, for example a stopper. Alternatively, the solid formulations of the disclosure~~invention~~ may be provided in a jar or other container with a removable and replaceable lid, or in a bag or within a wrapper (for example a foil wrapper). A desiccant is preferably also present. Alternatively, they may be packaged in a blister pack. In an example~~embodiment~~, the solid formulations are packaged within a tube, jar, bag, wrapper or other container without any wrapping around individual units (e.g. tablets). Optionally, individual units of solid formulations of the present disclosure~~invention~~ may have a wrapping. In a preferred example~~embodiment~~, 30 units of the formulation of the present disclosure~~inventions~~ are provided spilt into three tubes (e.g. 10 units per tube) or other packaging optionally together with instructions for use. Units of the present disclosure~~invention~~ may also be provided in a refill bag enabling previously obtained tubes to be refilled with units of the disclosure~~invention~~.

The solid formulations of the disclosure~~invention~~ can be taken on their own as presented and chewed or sucked by a subject. It is not necessary for a subject to take water or another drink with the solid formulation. Some subjects may wish to drink water or another fluid with or soon after taking a solid formulation of the disclosure~~invention~~ so as to facilitate the intake. The convenient packaging and the lack of a need to take water or another drink greatly increases the convenience of the solid formulations to subjects in comparison with other forms of PEG-based products currently on the market. Formulations of the present

disclosure~~invention~~ may be consumed prior to eating a meal or snack, together with the meal or snack or following a meal or snack.

In one example~~mbodiment~~, a solid formulation of the invention may be used to prevent gastrointestinal disorders. The formulation may be particularly beneficial for maintenance of good health, in particular maintenance of good gastrointestinal health. It may, for example, prevent dehydration of the stool, soften the stool for ease of defaecation, prevent constipation and allow regular gastrointestinal transit. The solid formulation of the disclosure~~invention~~ may be used to promote stool softening, increase stool weight and/or increase stool frequency in healthy subjects. Improvement of those features may lead to an increased sensation of well-being.

The disclosure~~invention~~ thus provides a method of preventing gastrointestinal disorders in a healthy subject, for example softening the stool, increasing stool weight and/or increasing stool frequency, preventing dehydration of the stool, softening the stool for ease of defaecation or preventing constipation in a healthy subject, comprising administering a solid formulation according to the disclosure~~invention~~. In particular, it provides a method of non-therapeutically preventing gastrointestinal disorders in a healthy subject, for example softening the stool, increasing stool weight and/or increasing stool frequency, preventing dehydration of the stool, softening the stool for ease of defaecation or preventing constipation in a healthy subject.

As used herein the term "non-therapeutic" and grammatical variations thereof means that the formulations of the present disclosure~~invention~~ preferably do not have a measurable pharmacological, immunological or metabolic effect on the body.

Formulations of the present disclosure~~invention~~ may be particularly suited for subjects of more than 50 years of age, for example more than 60, 65 or 70 years of age. Healthy subjects of the present disclosure~~invention~~ may be those who are particularly susceptible to episodes of constipation and wish to delay or reduce the frequency of such episodes or prevent the onset of constipation. By doing so, formulations of the present disclosure~~invention~~ may reduce the

need for such subjects to seek more interventional measures to treat constipation such as the use of laxatives. Formulations of the disclosure~~invention~~ may also prevent straining at stool which may be particularly beneficial for subjects who are healthy (i.e. have normal bowel movement) but are hypertensive where such straining carries a degree of risk to the subject.

Subjects of the present disclosure~~invention~~ are mammals and typically human.

In one example~~embodiment~~, the subject typically takes up to 6g (or thereabout) per day of PEG, for example 2 to 6g per day, for example 3 to 5g per day, for example 4 to 5g per day. In that example~~embodiment~~, the formulation is free from components of a nature and quantity having a laxative effect. PEG is not considered to have significant laxative activity in an adult when taken at a level of 6g per day. Mannitol, flavouring and lubricant components are also not considered to have significant laxative activity at the daily levels at which they are provided when the formulation provides up to 6g PEG per day. For a solid formulation of 2.0 to 3.5g total mass and comprising 85% PEG w/w, a healthy subject may be recommended to take 1 or 2, or 1, 2 or 3 per day (to provide up to 6g or thereabout of PEG per day). For a smaller solid formulation (of, for example, 1.0 to 1.75g total mass), a healthy subject may be recommended to take 1 to 6 per day, for example 2 to 5 per day (to provide up to 6g or thereabout of PEG per day). Conversely, for a larger solid formulation (of, for example, total 3.0 to 7.0g total mass), a healthy subject may be recommended to take 1 or 2 per day (to provide up to 6g or thereabout of PEG per day).

Formulations of the present disclosure~~invention~~ are particularly suited in enabling the subject to consume up to 6g (or thereabout) of PEG on a chronic basis. Preferably, the formulations of present disclosure~~invention~~ enable a healthy subject to consume 4 to 5 g (for example 4g or thereabout) of PEG per day Such an amount of PEG, taken on a chronic (e.g. daily) basis, has the advantages mentioned *supra* in terms of preventing gastrointestinal disorders, (particularly those related to defecation), and maintaining gastrointestinal health without causing excessive gastrointestinal disturbances (for example loose stools).

While consuming a higher amount of PEG (for example 10g or more) on a chronic basis may be effective in preventing or indeed treating disorders of the gastrointestinal system, such an amount is likely to produce undesirable gastrointestinal disturbances. As mentioned *supra*, if the subject consuming such higher amounts of PEG are otherwise healthy, they may be more likely to discontinue consumption regardless of any benefit in continuing, if such consumption is uncomfortable, inconvenient or otherwise unpleasant.

Therefore, the present disclosure~~invention~~ provides a solid formulation for preventing gastrointestinal disorders or maintaining gastrointestinal health as described *supra* in a healthy subject which formulation is of a size that is not too large so as to be uncomfortable to consume, has good mouthfeel and ease of manufacture yet provides an effective amount of PEG without the need to consume so many units of the formulation so as to be bothersome. In doing so, the formulation of the present disclosure~~invention~~ enables chronic use on a daily or other regular basis by a healthy subject.

Thus, the present disclosure~~invention~~ provides a solid formulation for oral administration as a solid (preferably having a mass of 1.0 to 5.0g) to a healthy subject (such as a human) for use in a method of preventing gastrointestinal disorders or maintaining gastrointestinal health, for example for softening the stool, increasing stool weight and/or increasing stool frequency, preventing dehydration of the stool, softening the stool for ease of defaecation or preventing constipation,

wherein the formulation comprises:

(a) 50 – 90 % w/w (for example 60 to 90% w/w, preferably 70 to 90% w/w, more preferably 70 to 89 % w/w, for example 75 to 89 % w/w, e.g. 78 to 89 % w/w, 80 to 85% w/w, 81 to 85 % w/w, 80 to 84 % w/w, 82 to 84 % w/w) polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 10 – 40 % w/w (for example 10 to 25% w/w, 10 to 20% w/w, preferably 12 to 20 % w/w, more preferably 12 to 19% w/w, 12 to 18% w/w, or 12 to 17 % w/w, e.g.14 to 20% w/w, 14 to 19% w/w or 14 to 18% w/w 14 to 17% w/w) of a solid such as mannitol; together with

(c) optional lubricant, optional flavouring and/or optional sweetener as described supra; and

wherein the method comprises administering said formulation so that the subject consumes up to 6g (or thereabout) of PEG per day.

Preferably, said method comprises administering said formulation so that the subject consumes between 2g and 6g, e.g. 2g to 5.5g per day. Preferably, said method is performed on a daily or alternate day basis. Preferably the method is performed over a period of at least two weeks, preferably at least a calendar month, more preferably at least 6 consecutive calendar months, or at least 12 consecutive calendar months, or at least 24 or at least 36 consecutive calendar months.

The present disclosure~~invention~~ also provides a tablet comprising 2g of PEG 3350 or thereabout and raspberry-lemon or mint flavour for preventing gastrointestinal disorders, preventing dehydration of the stool, softening the stool for ease of defaecation, preventing constipation and allowing regular gastrointestinal transit. The subject may consume 1 to 2 tablets daily. The tablet may be part of a multi-tablet pack of e.g. thirty tablets. A multi-tablet pack, eg a cardboard box, may be further divided into or may itself contain containers each comprising e.g. ten tablets; for example, a cardboard box may contain three tubes, each containing ten tablets. The container(s), such as the tubes, preferably have tamper-evident seals. The pack and/or container(s) preferably further contain(s) instructions for use of the formulations. The instructions for use preferably instruct the subject to place individual tablets in the mouth and either chew or suck until they have fully dissolved; optionally, a glass of water can be drunk to help in the method.

PEG has also been described as being effective in preventing cancer of the colon and/or rectum (see EP1124566). Accordingly, in a further example~~embodiment~~, a solid formulation of the disclosure~~invention~~ may be used as a PEG-based composition treat or prevent cancer of the colon and/or rectum (for example colorectal cancer). A method of treating or preventing cancer of the colon and/or rectum in a subject comprising administering to the subject a solid formulation of the disclosure~~invention~~ is also provided. Suitable daily amounts of PEG to be

effective in this example~~embodiment~~ are for example 6.5g or more, for example 8.0g or more, for example 6.5 to 100g, for example 8 to 50g PEG per day. To achieve the desired amount of PEG, a subject may be administered a suitable number of solid formulations of the disclosure~~invention~~ of suitable PEG content. The number of solid formulations required depends on the concentration of PEG in the formulations and the mass of each solid formulation. A reduction in the total amount of PEG in each solid formulation brings about a pro rata increase in the number of solid formulations that a subject will need to take.

In this example~~embodiment~~, solid formulations of the disclosure~~invention~~ are preferably substantially free from components of a nature and quantity having a laxative effect, other than PEG and/or mannitol.

It will be apparent to the reader of this specification, that the term "comprising" and grammatical variations thereof, in relation to embodiments of the invention described *supra*, may instead be "consisting essentially of" or "consisting of".