

FOOD COMPOSITIONS FOR GUT HEALTH COMPRISING BLACK TEA

FIELD OF THE INVENTION

The present invention relates to the use of cooked food products comprising tea leaves, or a tea extract to promote intestinal micro-flora balance, to provide resistance against diarrhoea or to aid in the treatment of diarrhoea.

BACKGROUND OF THE INVENTION

Travelers' diarrhoea is a common problem for those travelling overseas. Current estimates are that 60 million travelers from the West visit high risk areas annually, and of these about 30-50% suffer bouts of diarrhoea. Furthermore, diarrhoeal diseases pose a heavy burden on developing countries, accounting for 1.5 billion bouts of illness a year, and are the second largest infectious killer among children under five years of age immediately after acute respiratory infections. Today, diarrhoeal diseases claim nearly two million lives a year among children under five years of age (WHO, 1999). There are two types of diarrhoea, infectious and non-infectious.

Some of the pathogens most strongly associated with diarrhoea are rotavirus, *Shigella* spp. and enterotoxigenic *Escherichia coli* (ETEC). Although problems occur mostly in children, travelers to areas of the world with poor hygiene are also at risk. Even those travelling within northern Europe, North America, or Australia are at increased risk (4-8% chance). The most important pathogens causing travelers' diarrhoea are ETEC and other *E. coli* types and *Shigella*. Tea can modulate the microflora inhibiting the growth of pathogens and may limit pathogen-induced fluid losses involved in diarrhoea.

Several suggestions have been made to use green tea to improve intestinal microflora balance in animals. N.Ishihara et al in Livestock Production Science, 68 (2001) pages 217-219 disclose that green tea extracts were added to the feed of calves and
5 showed moderate and wide-spectrum inhibitory effects on the growth of pathogenic bacteria which overall lead to an improvement in the microflora balance in the calves guts' and a decrease in the frequency of diarrhoea.

10 Bruneton in "Pharmacognosy, 2nd ed, chapter 5", 1999, Intercept LTD, Paris, discloses that the tea leaf can be used, orally, traditionally for the symptomatic treatment of mild diarrhoea.

It is also known to treat tea leaves for inclusion in food
15 products. EP-A-0 951 839 discloses treating fresh green tea leaves with a solution of water and a crystalline trehalose to obtain a treated tealeaf. The treated tea leaf may be incorporated into foods and avoids the need for frying food and thus increasing the fat content thereof. US 6,207,214 discloses
20 a process of making traditional Korean snacks comprising 80-95 %wt glutinous rice. The snacks may comprise 5 to 20 %wt of powdered green tea and they are steamed to produce the snack food. Neither of these two documents are concerned with health effects in the consumers of the food product.

25

JP 63169951 and JP 02265446 disclose jellies which may comprise tea.

JP 03168046 discloses the use of a tea extract with
30 cyclodextrin and/or a peptide in foods such as biscuits, cookies and jellies.

US 4 389 187 discloses the use of a black tea extract in a food susceptible to lipid oxidation.

It is also known in south east Asian cooking to include tea leaves in raw foods such as salads.

JP 06/056,689-A discloses food compositions for the prevention and treatment of infectious diarrhoea. The compositions comprise a chitin which contains a tea extract either adsorbed or chemically bonded therewith. When the tea is not bound with chitin, the compositions are said to have an unacceptable, bitter, taste.

However, a problem with these food compositions is that the level of unbound green tea which is taught to be possible to incorporate into the food product is very limited because the sensory properties, especially taste, of the food composition may be adversely affected by the tea.

The binding of the tea with a carrier, such as chitin, however brings further problems or disadvantages. Firstly, the bound tea leaves or tea extract are more expensive than their unbound equivalents and the material to which it is bound may not always be readily available. Also, the bound tea requires further processing and is not readily available at an affordable price in all countries. Furthermore, the bound tea then takes up some of the formulation space in the food product for a non-functional ingredient, thus, reducing the formulation space available for more functional ingredients. Moreover, chitin bound tea may be derived from animal sources which is not suitable for vegetarians and many of the inhabitants of countries in the developing world are vegetarians.

There is therefore still a need in the art for food compositions which can be used by all people to maintain or improve intestinal microflora balance and/or to treat or prevent diarrhoea.

5

Furthermore, there is also a need for such compositions which are effective and economical and relatively simple to produce. There is also a need for such compositions that fulfil one or more of the following criteria:

- 10 - they can be stored without refrigeration and have good keeping characteristics.
- they can be consumed as a part of the typical daily diet for all people,
- they can be consumed by all people,
- 15 - they do not require any further special preparation,
- they can be added to other food products,
- they can be made from readily available and economical ingredients,
- the ingredients they are prepared from do not need to be
- 20 pre-prepared with other materials.

The present invention seeks to address one or more of the above-mentioned problems.

25

SUMMARY OF THE INVENTION

We have surprisingly found that by the consumption of a food product which comprises unbound black tea, beneficial effects upon the maintenance or improvement of intestinal microflora

balance are obtained. This is especially true when the compositions are taken as a part of the daily diet. Furthermore, the food products are also beneficial in the treatment or prevention of infectious or non-infectious
5 diarrhoea.

The present invention therefore provides, according to a first aspect, the use of a cooked food product comprising black tea leaves, an extract of black tea or a mixture thereof, to
10 maintain or improve microflora balance and/or to treat or prevent diarrhoea in a subject consuming the composition and wherein the black tea leaves or the extract of black tea is/are present in an unbound state.

15 According to a second aspect the invention provides a cooked food product comprising black tea leaves, an extract of black tea or a mixture thereof, wherein the black tea leaves or the extract of black tea is/are present in an unbound state and further wherein the food product is a cookie, cake, bun,
20 pastry, or porridge which comprises a milk or milk based ingredient in an amount of up to 10 %wt.

The term "use of tea" and "tea" as used herein refers to the tea leaves, or of pieces of tea leaves, as the context
25 requires.

The amount of tea extract refers to the dry weight of the tea extract.

30 The food product is used to maintain or improve microflora balance and/or to treat or prevent diarrhoea (either infectious or non-infectious) in a subject consuming the composition.

Preferably the food product is consumed as a part of the subject's daily diet.

Preferably the black tea leaves, an extract of black tea or the
5 mixture thereof is/are cooked in the food product when it is cooked.

The products of the first aspect have several advantages. They can be used effectively by all people to maintain or improve intestinal microflora balance and/or to treat or prevent
10 diarrhoea. Also they are economical and can be made by conventional production methods using conventional apparatus. They can be stored without refrigeration and have good keeping characteristics, which is particularly important in developing countries where refrigerated storage facilities are often not
15 available and/or the climate is warm.

The food products can take many forms and are suitable for inclusion as a part of the daily diet to simply replace the non-tea containing equivalent. This means that they are readily
20 accepted into a daily diet by adults and children alike.

Furthermore, the food products can be prepared from readily available and economical ingredients (as long as a supply of tea or tea extract is available). Also, the tea can be used in
25 its conventional state of either the leaf or as an extract and does not require pre-processing with other ingredients before it can be added to the other ingredients of the food product.

Also, as the product is cooked, it can readily be added to other food products.

Without wishing to be bound by theory, it is believed that the polyphenols in the black tea leaves and tea extracts are able to inhibit the growth of both Gram-negative and Gram-positive pathogenic bacteria and viruses, which are major causative agents of intestinal infection leading to diarrhoea. This is achieved without adversely affecting beneficial gut bacteria, such as lactobacilli and bifidio bacteria, even at very high concentrations of the bacteria. Furthermore, it is believed that black tea leaves and tea extracts are able to limit pathogen- and enterotoxin-induced intestinal fluid losses in diarrhoea. Indeed the levels of beneficial bacteria in the gut may be increased to promote healthy microflora balance in the gut.

Thus the invention provides a beneficial effect upon the intestinal microflora balance and helps to improve or maintain this balance. This leads to health benefits for the individual consuming the food product and also helps to treat bouts of diarrhoea (infectious or non-infectious) or to prevent its occurrence. The invention is particularly effective for improving or maintaining intestinal microflora balance and the treatment or prevention of infectious diarrhoea.

Without wishing to be bound by theory, it is believed that the black tea may provide the effects referred to above by one or more of the following possible modes of action:

- complexation of iron, which is an essential micronutrient required for bacterial growth.

- disturbance of the membrane potential which leads to cessation of metabolic functions of the bacteria
- interaction with membrane proteins and block energy (glucose) transport into cells of the bacteria
- 5 • causing membrane damage and subsequent leakage of cell constituents into the environment
- inhibition of enterotoxin secretion from pathogens
- neutralisation of enterotoxin
- inhibition of pathogen-or enterotoxin induced chloride and
- 10 water transport to the gut wall.

According to the present invention, black tea (and extracts thereof) is advantageous in improving or maintaining intestinal microflora balance for the individual consuming the food

15 product and in treating bouts of diarrhoea (infectious or non-infectious) or preventing its occurrence. This may be because black tea is less likely to be absorbed in the gut than green tea because of its different chemical composition arising from the fermentation process which it undergoes as compared to

20 green tea. The beneficial effects may be due to the longer residence time of black tea in the gut compared to green tea.

Tea extracts have inhibitory (in vitro and in vivo) effect against *Vibrio cholerae*, *Salmonella typhi*, *Campylobacter*

25 *jejuni*, *Campylobacter Coli*, *Helicobacter pylori*, *Shigella*, *Salmonella*, *Clostridium*, *Pseudomonas*, *Candida*, *Mycoplasma* and *Cryptococcus*, rotavirus and influenza A virus growth, pathogen enterotoxin secretion and enterotoxin-induced intestinal fluid secretion.

30

This inhibitory may occur through one or more of the following active compounds in black tea and black tea extracts :

Catechins (present in low concentrations in black tea),
Theaflavins, Thearubigins, or condensed Tannins.

Except in the operating and comparative examples, or where
5 otherwise explicitly indicated, all numbers in this description
indicating amounts of material or conditions of reaction,
physical properties of materials and/or use are to be
understood as modified by the word "about." All amounts in the
food product are by weight, based on the weight of the food
10 product unless otherwise specified.

"The term "comprising" is meant not to be limiting to any
subsequently stated elements but rather to encompass non-
specified elements of major or minor functional importance. In
15 other words the listed steps, elements or options need not be
exhaustive. Whenever the words "including" or "having" are
used, these terms are meant to be equivalent to "comprising" as
defined above."

20 DETAILED DESCRIPTION OF THE INVENTION

The invention will now be discussed in greater detail.

Cooked food products

The food product can be any type of food product which is
25 subjected to a cooking process before being eaten so that the
food is eaten in a cooked and not in a raw state. The food
product may have been cooked by any cooking method including;
baking, frying, roasting, grilling, steaming, boiling or micro-
waving.

The tea or tea extract

The tea is used in the food product in an unbound state. As used herein "unbound state " means that the tea is used (either
5 as the leaf or as an extract of the tea, or as the mixture thereof) in a state in which it is not adsorbed or chemically bound to another material.

The tea leaf may be in a dried or non-dried form. It may be as
10 the whole leaf, as pieces of the leaf, or as particles produced from the leaf. The tea extracts are typically added to the food products as a liquid before the food products are cooked. The tea extract may be produced by any conventional method such as making an extract of the tea with hot or boiling water. The
15 tea extract may be of any strength.

The tea is a black tea. Any black tea may be used according to the invention. The term black tea as used herein also includes semi-fermented tea such as oolong. Green teas, which are not
20 fermented do not form a part of the present invention.

The food products, if they comprise the black tea leaf, preferably comprise an amount of from 0.01 to 25 %wt thereof, more preferably of from 0.1 to 15 %wt, most preferably of from
25 0.3 to 10 %wt. The food products, if they comprise the black tea extract, preferably comprise an amount of from 0.01 to 15 %wt thereof, more preferably 0.05 to 10 %wt, most preferably, 0.1 to 5 %wt. A mixture of both black tea leaf and black tea extract may be used. In this case, the products preferably
30 comprise each of these ingredients in the above stated amounts. If a mixture is used, it is especially preferred to use 0.5 to 10 %wt of the black tea leaf and 0.1 to 5 %wt of the black tea leaf extract.

For some food products it may be preferred to use the black tea extract, for example where the visual appearance of tea leaves is not desired in the food, or, where preparation of the food product is easier with the black tea extract.

Preferably the black tea leaves, an extract of black tea or the mixture thereof is/are cooked in the food product when it is cooked. However, it is also possible to add the tea leaves to the cooked food product after it has been cooked.

Dosage

The cooked food products are consumed in an amount sufficient to maintain or improve microflora balance and/or to treat or prevent diarrhoea (either infectious or non-infectious) in a subject consuming the composition and are preferably consumed as a part of the daily diet of an individual. The dosage required will depend upon the individual but may be, for example, in the range of from 1 to 50 mg/kg of body weight.

Types of food product

The cooked food product may be any type of cooked food product. It is especially preferred that the food product is either a cookie (biscuit); a bread product which can be either leavened (raised) or unleavened (unraised), such as leavened bread, tortilla, roti, chapati, nan bread, rye-bread; pastries; cake; bun; or a snack product such as a samosa, pastie, pie, pakora, crisps etc and cereal based products such as pasta and rice-based products.

The food product may be one which is mixed with a liquid such as milk or water during cooking. Examples of this type of edible composition include porridges and other such cooked

cereal products. Porridges are an especially preferred type of cooked food product according to the invention.

The present invention provides, in particular, a cooked food
5 product comprising black tea leaves, an extract of black tea or
a mixture thereof, wherein the black tea leaves or the extract
of black tea is/are present in an unbound state and further
wherein the food product is a cookie, cake, bun, pastry, or
porridge which comprises a milk or milk based ingredient in an
10 amount of up to 10 %wt.

It is especially preferred that the food product is one that
has good keeping qualities and which does not need
refrigeration, such as a dry cereal based product such as a
15 cookie. It is also preferred that the cooked food product does
not contain substantial amounts of water in order to extend its
keeping qualities. However, for food products such as pasta
and rice based products which are typically stored in the
substantially dried state and only cooked just prior to
20 consumption, it is not so important to have a low water content
in the cooked food product.

A food product according to the present invention does not
include drinks.

25 Water content

Preferably the cooked food product comprises 20 %wt water or
less, more preferably 15 %wt water or less. The exact amount
of water used will depend upon the type of the product and the
levels of the other ingredients used.

Food product ingredients

Any suitable ingredients may be used to produce the food product.

5 (i) Flour

The product will usually comprise a flour of some sort. The amount and type of flour will depend upon the food product. The flour may be made, for example, from cassava, wheat, beans, rice, maize, millet or oats. If desired the food product may
10 further comprise baking powder or any other raising agent.

(ii) Fat

The product will usually comprise a fat of some sort. The amount and type of fat will depend upon the food product. The
15 fat may be, for example, dairy-based such as butter, cream or cheese, a vegetable oil, animal oil, nut oil etc.

(iii) Milk or milk based ingredient

The product may comprise milk or milk based ingredient (not
20 butter as this is considered as a fat as referred to above). Suitable examples include, milk and milk powder, especially skimmed milk powder. The amount and type of the milk or milk based ingredient will depend upon the food product. For sweeter tasting food products, such as cookies, cakes, buns or
25 pastries the inclusion of a milk or milk based ingredient, especially skimmed milk powder, provides an especially pleasing taste to the food product in combination with the tea.

According to the second aspect of the invention, the milk or milk based ingredient is present in an amount of up to 5 or 10
30 %wt, more preferably of from 0.1 to 3 %wt, most preferably of from 0.5 to 2.5 % wt. in the food product.

(iv) Egg

The food products may also comprise egg in any suitable amount. The egg may be in the form of whole egg, egg whites, egg yolk or egg-derived products.

5

(v) Sugar

The food products may also optionally comprise one or more natural sweeteners (sugars). Suitable natural sweeteners include sucrose, fructose, glucose, maltose and mixtures thereof. Sucrose is especially preferred either alone or combination with another sugar. The amount of the sugar added is a matter of taste but will usually be in the range of from 1 to 25 %wt, preferably of from 2 to 20 %wt, most preferably 5 to 15%. In some cases sugar and/or fat free products may be used.

15

Other optional ingredients

The food products may contain any of the usual minor food ingredients in conventional amounts, for example: flavourings including herbs and spices, salt, pepper colourings, preservatives, flavour improvers, emulsifiers, stabilisers, artificial sweeteners, aromas etc. Typically these ingredients are used in an amount of 5 %wt or less per ingredient, with the product comprising less than 25 %wt in total of these ingredients.

25

Fruits and fruit pieces, vegetables and vegetable pieces, honey, cereals such as oats and rice, nuts etc may also be added to the food product to give flavour and/or texture. Depending upon the type of food product, it may comprise a fruit juice. Any desired fruit juice can be added. Typically amounts of up to 30 %wt in total of these ingredients may be added.

30

Production of the food product

The cooked food product may be produced by any suitable method for producing that type of food product. Suitable types of cooking methods are detailed above.

5

The present invention will be further explained with reference to the following non-limiting examples. Further examples within the scope of the present invention will be apparent to the person skilled in the art.

10

EXAMPLESExample 1

A cookie according to the present invention was made with the 15 formulation as given in table 1. The conventional method for making cookies was followed.

Table 1

	grams
Caster Sugar	170
Butter	170
Salt	5
Spices and flavouring	10
Baking powder	5
Skimmed milk powder	10
Tea Leaves	33
Plain Flour	450
Water	130

20 The cookies were found to have an acceptable taste and could be stored in an air-tight container for a prolonged period.

Regular consumption of the cookies has a beneficial effect upon intestinal microflora balance and can also be used to ameliorate diarrhoea infections in subjects consuming the 25 biscuits, including for infectious diarrhoea.

Example 2

In in-vitro experiments, black tea extract (1,5 mg/mL - 4,5 mg/mL) inhibited the growth of *Salmonella cholerasuis*,
5 *Staphylococcus aureus*, *Staphylococcus sonnei* and *Escherichia coli* K88.

Example 3

Anti-microbial properties have been attributed to tea.

10 Moreover, chewing tea was associated with improved resistance to enteric infections. To test the effect of black tea on acute infectious diarrhoea, black tea was infused to cannulated small intestinal segments of piglets infected with either enterotoxigenic *Escherichia coli* (ETEC) or *Escherichia coli*
15 heat-labile toxin (LT).

Spray-dried water extract of black tea-leaves was dissolved in osmotic solution. Black tea solutions with similar osmolality and pH were perfused (8 mL/h) into ETEC or LT-infected small intestinal segments of ETEC receptor-positive
20 piglets. After 8-h perfusion, changes in net fluid and electrolyte absorption were determined per cm². In addition, the capacity of black tea to inhibit LT-induced cytotoxicity was tested in a Vero cell-line. All data were expressed as mean $\pm$ least significant difference (LSD). Significance levels were
25 set at $P < 0.05$.

ETEC significantly impaired the intestinal net fluid absorption (171 ± 112 (-55%) versus 494 ± 112 $\mu\text{L}/\text{cm}^2$) as well as the net sodium and chloride absorption. Black tea dose dependently partially reversed ($P < 0.05$) significantly the ETEC-induced
5 reduction in net fluid (352 ± 112 (-20%) versus 171 ± 112 $\mu\text{L}/\text{cm}^2$ (-55%)), as well as net sodium and net chloride absorption. Black tea also significantly restored the LT-induced reduction in net fluid absorption (322 ± 112 (-27%) versus 494 ± 112 $\mu\text{L}/\text{cm}^2$), and net sodium and chloride absorption. In addition, black tea also
10 dose dependently inhibited the LT-induced cytotoxicity towards Vero cells.

Consuming black tea may be beneficial in treating secretory diarrhoea. Black tea probably not only acts against pathogen growth or adhesion, but also against enterotoxins or
15 enterotoxin-induced electrolyte transport changes and ensuing fluid secretion.

Claims

1. The use of a cooked food product comprising black tea leaves, an extract of black tea or a mixture thereof, to maintain or improve microflora balance and/or to treat or prevent diarrhoea in a subject consuming the composition and wherein the black tea leaves or the extract of black tea is/are present in an unbound state.
2. The use according to claim 1, wherein the black tea leaves, an extract of black tea or the mixture thereof is/are cooked in the food product when it is cooked.
3. The use according to either one of claims 1 or 2, wherein the product comprises 0.1 to 19 %wt of the black tea leaf.
4. The use according to any one of the preceding claims, wherein the product comprises 0.1 to 5 %wt of the black tea extract.
5. The use according to any one of the preceding claims, wherein the food product is either a cookie; a bread product: a pastry; cake; bun; a snack product or cereal based products.

6. The use according to any one of the preceding claims, which is a cookie, cake, bun or pastry, and which further comprises a milk or milk based ingredient in an amount of up to 10 %wt.
7. The use according to any one of the preceding claims, wherein the product comprises a mixture of black tea leaf and black tea extract.
8. The use according to claim 7, wherein the food product is consumed as a part of the subject's daily diet.
9. A cooked food product comprising black tea leaves, an extract of black tea or a mixture thereof, wherein the black tea leaves or the extract of black tea is/are present in an unbound state and further wherein the food product is a cookie, cake, bun, pastry, or porridge which comprises a milk or milk based ingredient in an amount of up to 10 %wt.