

A FOOD PRODUCT

Field of the Invention

The present invention relates to a food composition. More particularly, the present invention
5 relates to a food composition beneficial for gastrointestinal tract.

Background of the Invention

Food is the most suitable way to deliver benefits to the gastrointestinal tract which is one of the
vital internal organs of human body. When viruses enter the human body either through the
10 respiratory tract or by consuming food contaminated with such viruses, they cause disturbances
in the way the intestine (both small and large) works. This in turn causes an upset stomach,
diarrhea, stomach flu and other related problems.

More recently, SARS COV-2 (COVID 19), a coronavirus which has caused immense suffering in
15 the world, was also found to be causing gastrointestinal problems. One of the symptoms of
COVID 19 infection is found to be stomach related issues. Other than COVID 19, there are other
enveloped viruses which causes similar problems.

We have found that one of the ways human bodies can resist such viruses is by producing
20 Antimicrobial Peptides (AMPs). This is known to be human body's own defense mechanism.
However, a few interventions can boost human body's ability to enhance production of such
AMPs.

AMPs were initially discovered in insects and in animals and ever since their initial discovery
25 AMPs are regarded as promising antimicrobials. AMPs are ubiquitous in nature, and they typically
exhibit a broad spectrum of activity against invading bacteria, fungi, enveloped viruses and
parasites (Braff and Gallo, 2006). AMPs are generally short peptides and in humans about 90
different AMPs are reported to be present. AMPs, in general, have two major physical features
and they are - a) presence of cationic charge and b) a significant proportion of hydrophobic
30 residues. The cationic charge of the AMPs promotes selectivity for negatively charged microbial
cytoplasmic membranes whereas the hydrophobicity facilitates interactions with the cell
membrane of the microbial species.

It is thus an object of the present invention to provide for a food product for boosting Antimicrobial
35 Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract.

It is another object of the present invention to provide a food product for inactivation or killing of enveloped viruses in the intestinal epithelial cells of the gastrointestinal tract.

- 5 It is a further object of the present invention to provide a food product for boosting Antimicrobial Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract thereby inactivating or killing enveloped viruses in the intestinal epithelial cells of the gastrointestinal tract.

10 The present inventors while working on this have surprisingly found that a food product that comprises an edible peroxisome proliferator-activated receptor (PPAR) fatty acid e.g. a hydroxy fatty acid; together with a vitamin B3 compound or its precursors or analogues thereof is able to synergistically boost AMP generation in the intestinal epithelial cells of the gastrointestinal tract and thereby protecting against viruses.

15 Edible PPAR fatty acid as per this invention includes edible fatty acids which have a PPAR action and also includes their corresponding mono, di and triglyceride forms.

Summary of the Invention

In a first aspect the present invention provides for a food product comprising (i) a vitamin B3 compound or its precursors or analogues thereof; and (ii) an edible PPAR acid.

20

Preferred edible PPAR fatty acid is a hydroxy fatty acid having carbon atoms numbering from 6 to 20

25 In another aspect, the present invention provides for use of a food composition comprising vitamin B3 compound or its precursors or analogues thereof for boosting Antimicrobial Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract.

30 In yet another aspect, the present invention provides for use of a food composition comprising an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20 for boosting Antimicrobial Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract.

In yet another aspect. the present invention provides use of a food composition comprising,
a) a vitamin B3 compound or its precursors or analogues thereof; and,

- b) an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20,

for boosting AMPs in the intestinal epithelial cells of the gastrointestinal tract.

- 5 In yet another aspect, the present invention provides for use of a food composition comprising vitamin B3 compound or its precursors or analogues thereof for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.

- 10 In yet another aspect, the present invention provides for use of an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20 for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.

In a further aspect, the present invention provides for use of a food composition comprising,

- a) a vitamin B3 compound or its precursors or analogues thereof; and,
15 b) an edible PPAR fatty acid preferably a a hydroxy fatty acid having number of carbon atoms from 6 to 20,

for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.

20 **Detailed Description of the Invention**

- These and other aspects, features and advantages will become apparent to those of ordinary skill in the art from a reading of the following detailed description and the appended claims. For the avoidance of doubt, any feature of one aspect of the present invention may be utilized in any other aspect of the invention. The word "comprising" is intended to mean "including" but not
25 necessarily "consisting of" or "composed of." In other words, the listed steps or options need not be exhaustive. It is noted that the examples given in the description below are intended to clarify the invention and are not intended to limit the invention to those examples per se. Similarly, all percentages are weight/weight percentages unless otherwise indicated. Except in the operating and comparative examples, or where otherwise explicitly indicated, all numbers in this description
30 and claims 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". Numerical ranges expressed in the format "from x to y" are understood to include x and y. When for a specific feature multiple preferred ranges are described in the format "from x to y", it is understood that all ranges combining the different endpoints are also contemplated.

Enveloped virus as per the present invention includes a coronavirus or an influenza virus. Preferred coronavirus which may be treated as per the present invention is SARS-Cov2. Preferred influenza virus which may be treated as per the present invention is H1N1.

- 5 The present invention relates to a food product. By a "food product" is meant products for human consumption. It includes all foodstuffs, beverages, drinks and nutraceuticals that contains or consists of body nutrients, such as carbohydrates, fats, proteins, vitamins, minerals or similar ingredients which is ingested and assimilated to produce energy, stimulate growth and/or maintain life. When delivered as a nutraceutical it may be a vitamin/ mineral supplement in the
10 form of a tablet, capsule, gummy or powder.

- The present invention provides a food product comprising a vitamin B3 compound or its precursors or analogues thereof and an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20
15

- The most preferred vitamin B3 compound is niacinamide. This is also known as nicotinamide or as pyridine-3-carboxamide and is the active, water soluble form of vitamin B3. It is essential to the coenzymes NADH and NADPH and therefore for over 200 enzymatic reactions in the body including ATP formation.
20

- Precursors of vitamin B3 compounds are also within the scope of the present invention. The most preferred precursor being tryptophan.

- Analogues of vitamin B3 are also within the scope of the present invention. Nicotinamide, or
25 pyridine 3- carboxamide has 2 other positional isomers by substitution at 2, and 4 position of the pyridine ring, picolinamide (pyridine 2- carboxamide) and iso-nicotinamide (pyridine 4- carboxamide) respectively. These two are the most preferred analogues. Analogues of vitamin B3, as per this invention, also includes derivatives like cyclo alkyl nicotinamide with the cyclo alkyl group having 3 to 6 carbon atoms.

- 30 The vitamin B3 compound or its precursors or analogues are preferably included in 0.01 to 1%, more preferably 0.02 to 0.6%, further more preferably 0.05 to 0.4% by total weight of the food product.

The food composition of the present invention preferably comprises both the vitamin B3, its precursor or analogue thereof; and an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atom from 6 to 20.

Suitable examples of edible PPAR fatty acids as per this invention includes sapienic acid,
5 coriander seed oil, linoleic acid, conjugated linoleic acid, petroselinic acid and hydroxy fatty acids. Hydroxy fatty acids are derivatives of fatty acids containing a hydroxyl group at one or more positions. Preferably the fatty acids are saturated or unsaturated and branched or unbranched. The hydroxy fatty acids used in the present invention having 6 to 20 carbon atoms, preferably 8 to 20 carbon atoms, more preferably 10 to 16 carbon atoms, most preferably 10 to
10 14 carbon atoms. Hydroxy fatty acids as per this invention includes esters or precursors there. Esters may be of the C1-C6 alkyl esters. Precursors may be trihydroxy stearin or compounds that yield one or more molecules of hydroxystearic acid or hydroxystearate on their breakdown like mono, di or tri ester of glycerol with hydroxystearic acid.

Preferably the hydroxy fatty acid is selected from 2-hydroxymyristic acid, 3-hydroxymyristic
15 acid, 2-hydroxypalmitic acid, 3-hydroxypalmitic acid, 10-hydroxystearic, 12-hydroxystearic acid, 17-hydroxystearic acid, trihydroxystearic acid (e.g. 9,10,13-trihydroxystearic acid) or trihydroxy stearin or compounds that yield one or more molecules of hydroxystearic acid or hydroxystearate on their breakdown like mono, di or tri ester of glycerol with hydroxystearic acid.

20 Preferably the hydroxy fatty acid is hydroxystearic acid. The most preferred hydroxystearic acids are 10 hydroxystearic acid (10HSA) and 12 hydroxystearic acid (12HSA).

Alternately, instead of a hydroxy fatty acid, a natural source of hydroxy fatty acid may also preferably be used in the composition of the present invention.

The edible PPAR fatty acid is preferably included in 0.01 to 2%, more preferably 0.05 to 1%,
25 further more preferably 0.1 to 0.8% by total weight of the food product.

Without wishing to be bound by theory the inventors believe that the actives claimed in the present invention viz. Vitamin B3, its precursors and analogues thereof and the edible PPAR fatty acid e.g. 12-HSA activates host cells to help drive the defense benefit against non-enveloped viruses like SARS-Cov2. They believe that this mode of action is quite different from direct antivirals like
30 low boiling alcohols, bleaches and cationic surfactants like quaternary ammonium compounds which act directly on the virus particle to inactivate them thereby delivering the anti-viral benefit.

The food product of the present invention can practically be any type of food composition. The preferred ones are a tea beverage precursor, a cereal-based beverage precursor, a dressing, a frozen confection or a savoury concentrate.

- 5 When the product is a tea beverage precursor, it can be any kind of tea product e.g., black tea, green tea, white tea, or oolong tea . Also, the tea product can be in any format e.g., leaf tea, ready to drink tea, or liquid tea.

- 10 When the product is a savoury, it can preferably in a form of a savory concentrate. The savoury concentrate can suitably be used in the preparation of e.g., sauces, soups, or gravies., or it can be added to meal components as a seasoning. They are traditionally part of the daily diet in most countries, widely consumed and can be added to all kinds of foods.

- 15 According to a particularly preferred embodiment, and especially where the concentrate is a savoury concentrate, the concentrate comprises at least 0.5% amino acids by weight of the concentrate. More preferably, the concentrate comprises from 1 to 35% amino acids, most preferably 5 to 30% amino acids. The amino acids can be selected from one or more taste-imparting amino acid or salt thereof. Particularly preferred are one or more amino acids selected from alanine, aspartate, glutamate, glycine, histidine, isoleucine, leucine, lysine, methionine, 20 phenylalanine, proline, serine, theanine, tyrosine, tryptophan, and valine. Especially preferred is glutamate owing to its ability to impart an umami taste.

- The sugars that can be used as taste-imparting component are preferably selected from monosaccharides, disaccharides and combinations thereof. More preferably the sugars are 25 selected from sucrose, glucose, fructose, maltose, lactose and mixtures thereof. More preferably still the sugars are selected from sucrose, glucose, fructose and mixtures thereof. Most preferably the sugars comprise sucrose. The sugars may be included in the concentrate in substantially refined form and/or may be present as part of more complex ingredients of the concentrate such as, for example, cereal materials, maltodextrins, glucose syrups, milk powders and the like.

30

Preferably the concentrate comprises the sugars in an amount of from 1 to 50% by weight of the concentrate, more preferably from 2 to 40%, more preferably still from 3 to 30% and most preferably from 4 to 20%.

The term "fat" as used herein refers to fatty acid glycerol ester selected from triglycerides, diglycerides, monoglycerides, phosphoglycerides and combinations thereof.

5 The concentrate of the present invention preferably contains at least 1% fat by weight of the concentrate. More preferably, the concentrate contains 3 to 40% fat, most preferably 5 to 30% fat. The fat contained in the concentrate may be liquid, semi solid or solid. Preferably, the fat contained in food concentrate has a solid fat content at 20°C (N₂₀) of from 0 to 95%. Even more preferably, the fat has a N₂₀ of at least 10% and most preferably the fat has a N₂₀ of 25 to 90%. The solid fat content of the fat can suitably be determined using the method described in Animal
10 and vegetable fats and oils -- Determination of solid fat content by pulsed NMR -- Part 1: Direct method - ISO 8292-1:2008.

Preferably the fat comprises palm oil, palm kernel oil, fractionated palm oil, palm oil stearin, fully hydrogenated palm oil, shea oil, shea butter, shea oil stearin, coconut fat, cacao butter, tallow,
15 chicken fat, butter fat, sunflower oil, rapeseed oil, soybean oil, linseed oil, olive oil or combinations of two or more thereof.

The savoury concentrate preferably comprises at least 1% polysaccharide by weight of the concentrate. More preferably, the concentrate contains 3 to 60% polysaccharide, most preferably
20 5 to 50% polysaccharide. The polysaccharide may be a substantially refined polysaccharide such as a gum (e.g. guar gum, locust bean gum, xanthan gum, tara gum, gellan gum and mixtures thereof) and/or starch. Additionally or alternatively the polysaccharide may be part of a complex ingredient of the concentrate such as, for example, flour.

25 The savoury concentrates are preferably dry, wherein "dry" means that they comprise no more than 20% water by weight of the concentrate. The water content of the concentrate preferably does not exceed 10% by weight of the concentrate, more preferably does not exceed 8% and even more preferably the water content is from 0.01 to 6% by weight of the concentrate.

30 The water activity (at 20°C) of the concentrate is preferably in the range of 0.1 to 0.6. More preferably, the water activity is in the range of 0.1 to 0.4, most preferably in the range of 0.1 to 0.2.

The savoury concentrate preferably comprises a table salt in addition to the multimineral salt
35 particles. By "table salt" is meant salt comprising NaCl, KCl and mixtures thereof, most preferred

is NaCl. Preferably, the amount of table salt in the concentrate is at least 3% by weight of the concentrate, more preferably at least 5%, even more preferably at least 8%, still more preferably at least 10%, yet more preferably at least 15%, and even still more preferably at least 20%. Preferably, the amount of table salt is at most 70% by weight of the concentrate, more preferably at most 60%, even more preferably at most 50%, and still more preferably at most 40%. Preferably, the amount of NaCl in the savoury concentrate is at least 3% by weight of the concentrate, more preferably at least 5%, even more preferably at least 10%, still more preferably at least 15% and preferably at most 60%, more preferably at most 55%, and still more preferably at most 50%.

10

Where the concentrate is a savoury concentrate, the polysaccharide in the concentrate preferably comprise a starch component selected from native (ungelatinized) starch, pregelatinised starch, maltodextrin, modified starch and combinations thereof. The starch component is preferably present in the savoury concentrate in a concentration of 3 to 50% by weight of the concentrate, more preferably of 4 to 30% and most preferably of 5 to 25%. The starch component is preferably selected from native starch, maltodextrin, pregelatinised starch and combinations thereof. Even more preferably, the starch is selected from native starch, pregelatinised starch and combinations thereof. Most preferably, the starch component is native starch. The starch component typically has a mass weighted mean diameter in the range of 5-200 μm , more preferably of 10-100 μm , most preferably of 12-60 μm .

20

In a preferred embodiment, the savoury concentrate comprises:

- 5 to 30% fat by weight of the concentrate; and

- 35 to 75% of total inorganic salt by weight of the concentrate, wherein the total inorganic

salt comprises the multimineral iron-containing particles.

25

The inorganic salt preferably comprises, consists essentially of or consists of a mixture of table salt and the multimineral iron-containing particles. Preferably the inorganic salt comprises table salt in an amount of at least 50% by weight of the inorganic salt, more preferably at least 70%, more preferably still at least 85%, even more preferably at least 90% and most preferably from 95 to 99%.

30

In an alternative embodiment, the savoury concentrate may be formulated to provide a savoury taste without containing substantial amounts of table salt. Thus, in a preferred embodiment the savoury concentrate comprises:

35

- 10 to 35% fat by weight of the concentrate;
- 10 to 50% ungelatinized starch by weight of the concentrate;
- 10 to 50% by weight of the concentrate of an oligosaccharide-containing material selected from dry glucose syrup, maltodextrin and combinations thereof.

5

In some embodiments the concentrate may be a beverage precursor. Preferred are tea-based beverage precursors or cereal-based beverage precursors. Particularly preferred are precursors of cereal-based beverages as cereal-based beverages have good opacity and strong flavour that forms a robust base for masking any organoleptic effects of the multimineral particles. The preferred beverage precursors comprise 20 to 80% cereal material by weight of the concentrate. By "cereal material" is meant material derived from a cereal plant, especially a cereal plant selected from one or more of wheat, barley, rye, maize, rice, sorghum, millet and oats. The material may be flour, starch, extract or a mixture thereof. In a preferred embodiment, at least part of the cereal material is malted. Especially preferred is malted wheat, barley or a mixture thereof. Cereal material typically contributes a significant amount of polysaccharide to the concentrate and so the beverage precursor may contain at least 10% polysaccharide by weight of the concentrate, preferably at least 20% and most preferably 30 to 60% polysaccharide by weight of the concentrate.

20 The most preferred cereal-based beverage precursor composition comprised of wheat flour, barley malt, milk solids, sugar and minerals.

The cereal-based beverage precursor composition also may be in the form of a supplement or health drink composition.

25

In some embodiments the concentrate is a dietary supplement such as a pill, lozenge, tablet or the like.

30 Preferably, the food product whether in form of a concentrate or not can come in several forms or shapes: typical forms are free-flowing powders, granulates, shaped concentrates and pastes.

According to a particularly preferred embodiment of the present invention is a shaped article, notably a shaped solid article. Examples of shaped solid articles include concentrates in the form of cubes, tablets or granules.

35

The shaped article preferably has a mass in the range of 1 to 50 g, more preferably in the range of 2.5 to 30 g and most preferably of 3.2 to 24 g. The shaped article can suitably be provided in different forms. Preferably, the article is provided in the form of a cuboid, more preferably in the form of a rectangular cuboid and most preferably in the form of a cube.

5

The food product of the present invention preferably is preferably a packaged concentrate. Where the concentrate is a savoury concentrate in the form of a shaped article, it is preferred that the article is packaged in a wrapper.

- 10 The present invention also provides for use of a food composition comprising vitamin B3 compound or its precursors or analogues thereof for boosting Antimicrobial Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract.

The present invention also provides for use of a food composition comprising,

- 15 a) a vitamin B3 compound or its precursors or analogues thereof; and,
b) an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20,

for boosting AMPs in the intestinal epithelial cells of the gastrointestinal tract.

- 20 The present invention further provides for use of a food composition comprising vitamin B3 compound or its precursors or analogues thereof for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.

The present invention yet further provides for use of a food composition comprising,

- 25 a) a vitamin B3 and compound or its precursors or analogues thereof; and,
b) an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20,

for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.

30

The following examples are intended to illustrate the invention and are not intended to limit the invention to those examples *per se*.

35

Examples

Examples A, 1-3: Effect of 12-HSA and niacinamide and a combination on intestinal epithelial cell (Caco-2 cells)

The Caco2 cells were plated in 24 well plate at equal density and allowed to grow till 90%

- 5 confluence. The mentioned compound was added at their respective concentrations and cells were incubated for 48 hr before they were harvested in trizol. After routine RNA isolation and cDNA synthesis, LL37 (an AMP) mRNA levels were measured using qPCR. The data was normalized with bActin and converted to fold change. The data is presented in Table -1 below:

10 Table - 1

Example	Sample	LL37 (change over control)
A	Control (DMSO)	---
1	Niacinamide (16.4 mM)	1.56
2	12 HSA (20 mM)	0.97
3	12HSA (20mM) + niacinamide (16.4 mM)	2.67

The data in table -1 above indicates that the actives niacinamide and 12-HSA and their combination are capable of boosting Antimicrobial Peptides (AMPs) in the intestinal epithelial cells of the gastrointestinal tract, thereby providing for killing or inactivation of enveloped virus.

Claims

1. A food product comprising
 - (i) a vitamin B3 compound or its precursors or analogues thereof; and
 - (ii) an edible PPAR fatty acid.
2. A food product as claimed in claim 1 wherein the edible PPAR fatty acid is a hydroxy fatty acid having number of carbon atoms from 6 to 20.
3. The food product as claimed in claim 1 or 2 wherein the vitamin B3 compound or its precursors or analogue is selected from tryptophan, niacinamide, iso-niacinamine, picolinamide, cyclo alkyl nicotinamide with the cyclo alkyl group having 3 to 6 carbon atoms and combinations thereof.
4. The food product as claimed in claim 2 or 3 wherein the hydroxy fatty acid is selected from hydroxystearic acid (HSA) preferably 12-hydroxystearic acid or 10-hydroxystearic acid.
5. The food product as claimed in any one of the preceding claims, wherein the food product is a tea beverage precursor, a cereal-based beverage precursors, a dressing, a frozen confection or a savoury concentrate.
6. The food product as claimed in claim 5 wherein the product is a savoury concentrate comprising:
 - a) 5 to 30% fat by weight of the concentrate; and
 - b) 35 to 75% of total inorganic salt by weight of the concentrate.
7. The food product as claimed in claim 5 wherein the product is a savoury concentrate composition comprising:
 - a) 10 to 35% fat by weight of the concentrate;
 - b) 10 to 50% ungelatinized starch by weight of the concentrate;
 - c) 10 to 50% by weight of the concentrate of an oligosaccharide-containing material selected from dry glucose syrup, maltodextrin and combinations thereof.
8. The product as claimed in claim 5 wherein the cereal-based beverage precursor comprises one or more of wheat flour, barley malt, milk solids, sugar and minerals.

9. Use of a food composition comprising,
 - (a) a vitamin B3 compound or its precursors or analogues thereof; and,
 - (b) an edible PPAR fatty acidfor boosting AMPs in the intestinal epithelial cells of the gastrointestinal tract.
10. Use as claimed in claim 9 wherein the edible PPAR fatty acid is a hydroxy fatty acid having number of carbon atoms from 6 to 20.
11. Use of a food composition comprising,
 - a) a vitamin B3 compound or its precursors or analogues thereof; and,
 - b) an edible PPAR fatty acid preferably a hydroxy fatty acid having number of carbon atoms from 6 to 20,for inactivation or killing of enveloped virus in the intestinal epithelial cells of the gastrointestinal tract.