

MARINE ALGAE REHYDRATION COMPOSITIONS AND METHODS

[0001] The present invention claims priority to United States Provisional Patent Application No. 63/492,579, filed on March 28, 2023, the entirety of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention relates to rehydration compositions comprising water, at least one electrolyte, and a marine algae polysaccharide, as well as methods for providing rehydration by orally administering a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide, or specifically fucoidan.

BACKGROUND OF THE INVENTION

[0003] Current oral electrolyte solutions are used to promote rehydration and electrolyte replacement in both pediatric and adult populations. These solutions provide a balance of sodium, glucose and water to promote fluid and electrolyte adsorption and provide rehydration in individuals faster than rehydration with water alone. However, while these electrolyte solutions provide better rehydration than water alone, loss of water often still occurs through a stressed intestinal barrier in the gut.

[0004] In view of the above, there is a need to develop new and accessible technologies that can conveniently provide improved rehydration with food and beverage products.

SUMMARY OF THE INVENTION

[0005] It is therefore an object of the invention to provide improved rehydration compositions and methods that provide a better hydrating ability than conventional compositions and methods through the surprising effect of a marine algae polysaccharide, or specifically, fucoidan.

[0006] In one embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide.

[0007] In another embodiment, the invention is directed to a method of rehydrating a subject comprising administering a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide, to the subject.

[0008] In another embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and fucoidan.

[0009] In another embodiment, the invention is directed to a method of rehydrating a subject comprising administering a rehydration composition comprising water, at least one electrolyte, and fucoidan, to the subject.

[0010] In another embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide, or specifically fucoidan, in an effective amount to provide the composition with an improved hydrating effect.

[0011] In another embodiment, the invention is directed to a method of rehydrating a subject comprising administering a rehydration composition comprising water, at least one electrolyte, and fucoidan, to the subject, wherein the fucoidan is effective to improve the hydrating effect of the composition.

[0012] In another embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide, or specifically fucoidan, wherein the composition is configured to increase an amount of water and electrolyte that enters a blood stream of the subject, a rate at which water and electrolyte enters a blood stream of the subject, or both (compared to consumption of the same amount of an identical rehydration composition but without the marine algae polysaccharide, or specifically fucoidan) when consumed orally.

[0013] In another embodiment, the invention is directed to a method of rehydrating a subject comprising administering a rehydration composition comprising water, at least one electrolyte,

and a marine algae polysaccharide, or specifically fucoidan, to the subject, wherein an amount of water and electrolyte(s) that enters a blood stream of the subject, the rate at which water and electrolyte(s) enters a blood stream of the subject, or both, is increased compared with an administration of the same amount of an identical rehydration composition but without a marine algae polysaccharide, or specifically fucoidan.

[0014] In another embodiment, the invention is directed to a method of improving the hydrating effect of a rehydration composition comprising water and at least one electrolyte through the inclusion of a marine algae polysaccharide, or specifically fucoidan.

[0015] In another embodiment, the invention is directed to a use of a marine algae polysaccharide, or specifically fucoidan, to improve the hydrating effect of a rehydration composition comprising water and at least one electrolyte.

[0016] The addition of marine algae polysaccharide, or specifically, fucoidan, to rehydration compositions provides a surprising means for providing improved rehydration. These and additional objects and advantages of the invention will be more fully apparent in view of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The drawings are illustrative of certain embodiments of the invention and are exemplary in nature and are not intended to limit the invention defined by the claims, wherein:

[0018] **FIG. 1** illustrates water absorption in model intestinal epithelial cells obtained with a rehydration composition according to the invention compared to that obtained with a rehydration composition according to the prior art, as described in Example 1.

[0019] **FIG. 2** illustrates water absorption in model intestinal epithelial cells obtained with a rehydration composition according to the invention compared to that obtained with a rehydration composition according to the prior art, as described in Example 2.

[0020] **FIG. 3** illustrates moisture uptake in an embodiment of a powdered rehydration composition containing fucoidan according to the invention compared to that of a powdered rehydration composition according to the prior art, as described in Example 3.

DETAILED DESCRIPTION

[0021] Specific embodiments of the invention are described herein. The invention can, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided to illustrate more specific features of certain embodiments of the invention to those skilled in the art.

[0022] The terminology as set forth herein is for description of the embodiments only and should not be construed as limiting the disclosure as a whole. All references to singular characteristics or limitations of the present disclosure shall include the corresponding plural characteristic or limitation, and vice versa, unless otherwise specified or clearly implied to the contrary by the context in which the reference is made. Unless otherwise specified, “a,” “an,” “the,” and “at least one” are used interchangeably. Furthermore, as used in the description and the appended claims, the singular forms “a,” “an,” and “the” are inclusive of their plural forms, unless the context clearly indicates otherwise.

[0023] To the extent that the term “includes” or “including” is used in the description or the claims, it is intended to be inclusive of additional elements or steps, in a manner similar to the term “comprising” as that term is interpreted when employed as a transitional word in a claim. Furthermore, to the extent that the term “or” is employed (e.g., A or B), it is intended to mean “A or B or both.” When the “only A or B but not both” is intended, then the term “only A or B but not both” is employed. Thus, use of the term “or” herein is the inclusive, and not the exclusive use. When the term “and” as well as “or” are used together, as in “A and/or B” this indicates A or B as well as A and B.

[0024] All ranges and parameters, including but not limited to percentages, parts, and ratios disclosed herein are understood to encompass any and all sub-ranges subsumed therein, and every number between the endpoints. For example, a stated range of “1 to 10” should be considered to include any and all sub-ranges beginning with a minimum value of 1 or more and ending with a maximum value of 10 or less (e.g., 1 to 6.1, or 2.3 to 9.4), and to each integer (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) contained within the range.

[0025] Any combination of method or process steps as used herein can be performed in any order, unless otherwise specified or clearly implied to the contrary by the context in which the referenced combination is made.

[0026] All percentages are percentages by weight unless otherwise indicated.

[0027] The term “subject” or “individual”, as used herein, unless otherwise specified, refers to a human pediatric or adult individual. In specific embodiments, the subject can be recovering from exercise as such subjects are typically in need of rehydration.

[0028] The term “rehydration composition” as used herein, unless otherwise specified, refers to rehydration liquids and rehydration powders, the latter of which may be reconstituted or otherwise mixed with a liquid, for example, water, in order to form a rehydration liquid, and are suitable for oral consumption by a human. Rehydration liquids may be prepared in ready-to-drink (RTD) form or may be reconstituted from powder as described.

[0029] The term “heat sterilized” as used herein, unless otherwise specified, refers to a liquid rehydration composition which has been thermally processed at an elevated temperature for a period of time sufficient to achieve a sufficient reduction in microorganisms to provide storage stability of the composition. In certain embodiments of the invention, liquid rehydration compositions are first heat sterilized and then packaged into sterilized bulk containers. In other embodiments of the invention, the liquid rehydration compositions may be packaged in a container, followed by heat sterilization of the packaged composition. Suitable containers

include, for example, metal (e.g., aluminum) cans and bottles, glass bottles, and plastic containers (e.g., plastic bottles).

[0030] The term “electrolyte” as used herein, unless otherwise specified, refers to ions that carry an electric charge. The electrically charged ions come from mineral compounds that break up into ions when corresponding mineral compounds are dissolved in water or bodily fluids. Examples of electrolytes include, but are not limited to, sodium, potassium, calcium, chloride, and phosphate.

[0031] The term “milliequivalent” (mEq) as used herein, unless otherwise specified, refers to the number of electrolyte ions in a given volume of solution. One equivalent of an electrolyte (e.g., sodium) is the atomic mass of that electrolyte divided by its valence. The number of milliequivalents of a given electrolyte in a given volume is the weight of the electrolyte (in milligrams) multiplied by its valence and divided by its atomic mass. This measure is typically expressed as the number of milliequivalents per liter (mEq/L). Milliequivalents may be converted to milligrams by multiplying mEq by the atomic mass of the electrolyte and then dividing that number by the valence of the electrolyte.

[0032] The term “seaweed” is the common name for countless species of marine plants and algae that grow in the ocean as well as in rivers, lakes, and other water bodies. “Seaweed polysaccharide” as used herein, unless otherwise specified, refers to complex carbohydrates produced in marine plants and algae. Marine algae and algal seaweed are used interchangeably herein and include three main categories: green algae, red algae and brown algae. Green algae includes varieties such as, but not limited to, *Monostroma*, *Ulva*, *Caulerpa*, and *Chlorella*. Red algae includes varieties such as, but not limited to, *Gracilaria*, *Porphyra*, and *Eucheuma*. Brown algae includes varieties such as, but not limited to, *Laminariaceae*, *Undaria*, and *Sargassum*.

[0033] Fucoidan is an example of a marine algae, or algal seaweed, polysaccharide. It forms a protective coating on the marine algae varieties. Fucoidan is a long chain partially

sulfated polysaccharide that can be derived from brown and other algae varieties, including *Fucus vesiculosus*, *Undaria pinnatifida*, and other marine plants, materials, or marine algae organisms cultivated commercially.

[0034] Specific embodiments of the invention include fucoidan from marine algae. More specific embodiments of the invention include fucoidan from brown marine algae. In a specific embodiment, the fucoidan is derived from an *Undaria* brown algae. In another specific embodiment, the fucoidan is derived from a *Fucus* brown algae.

[0035] The fucoidan may desirably be provided in a non-hydrolyzed, i.e. fully intact, form. Without being bound by theory, it is believed that in its intact form, fucoidan acts to bond water molecules (and the water-soluble electrolyte(s)) and deliver them to the absorptive surface of the epithelium, thereby contributing to the improved rehydration effect disclosed herein. If the size of the fucoidan molecules is reduced, e.g. through hydrolysis, then it is believed that the resulting lower molecular weight molecules will have a lesser effect, or possibly no effect at all, in bonding and delivering the water in this manner.

[0036] For instance, intact fucoidan is highly hygroscopic due to the potential for interaction between hydroxyl groups and sulfate groups inherent in the structure of fucoidan with water molecules, which have weak polar charge. These interactions are individually weak but very potent when present in large numbers. Hydrolyzed low molecular weight fucoidan fragments would be expected to carry much lower hygroscopic potential. Further, intact fucoidan has a high molecular weight and charge, which prevents its passage through the intestinal lining. This permits sustained interaction between the fucoidan molecule and the absorptive surface of the epithelium which is thought to contribute to the proposed rehydration properties. Hydrolyzed fucoidan would have a low molecular weight, which may limit its potential to interact with the intestinal surface and instead permit increased transfer across the intestinal lining.

[0037] As indicated above, the present invention provides rehydration compositions and methods.

[0038] In one embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide.

[0039] In another embodiment, the invention is directed to a method of rehydrating a subject, comprising orally administering a rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide.

[0040] In yet another embodiment, the invention is directed to a rehydration composition comprising water, at least one electrolyte, and fucoidan. In another embodiment, the invention is directed to a method of rehydrating a subject, comprising orally administering a rehydration composition comprising water, at least one electrolyte, and fucoidan.

[0041] The rehydration composition may be consumed as a ready to drink liquid or may be formed as a liquid by reconstitution of a powder composition. If the rehydration composition is reconstituted from a powder, for example, a serving size from about 40 g to about 60 g, such as 45 g, or 48.6 g, or 50 g, of powder may be reconstituted in from about 1 ml to about 500 ml of liquid, or, in a more specific embodiment, from about 150 to about 450 ml of liquid, or from about 200 to about 400 ml of liquid, for example, water. Alternatively, a serving size of between about 3.5 g and about 17 g of powder may be reconstituted in from about 236 ml (8 fluid ounces) to about 474 ml (16 fluid ounces) of liquid, e.g. water. As an example, a serving size of about 8.5 g of powder may be reconstituted in about 236 ml of liquid, e.g. water.

[0042] A serving size of the liquid rehydration composition, reconstituted from a powder or manufactured as a ready-to-drink product, ranges from about 1 ml to about 500 ml, including from about 100 ml to about 500 ml, from about 110 ml to about 417 ml, from about 120 ml to about 500 ml, from about 120 ml to about 417 ml, from about 177 ml to about 417 ml, from about 207 ml to about 296 ml, from about 230 m to about 275 ml, from about 200 ml to about 300 ml, from about 110 ml to about 237 ml, from about 120 ml to about 245 ml, from about 110 ml to about 150 ml, and from about 120 ml to about 150 ml. In specific embodiments, the serving is about 100 ml, or about 225 ml, or about 237 ml, or about 360 ml, or about 500 ml.

[0043] As mentioned above, in specific embodiments of the invention, the marine algae polysaccharide, or specifically, the brown marine algae polysaccharide, comprises fucoidan. The fucoidan is included in the rehydration composition in an amount sufficient to provide enhanced rehydration benefits.

[0044] If the rehydration composition is in the form of a liquid, the rehydration composition may comprise at least about 0.0001 µg/ml, or at least about 0.001 µg/ml, or at least about 0.01 µg/ml, or at least about 0.1 µg/ml, or at least about 1 µg/ml, or at least about 5 µg/ml, or at least about 10 µg/ml, or at least about 50 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. Similarly, the rehydration composition may comprise less than about 500 µg/ml, or less than about 400 µg/ml, or less than about 300 µg/ml, or less than about 200 µg/ml, or less than about 150 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan.

[0045] In a specific embodiment of the invention, the liquid rehydration composition comprises about 0.0001-15 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In another specific embodiment, the liquid rehydration composition comprises about 0.001-450 µg/ml, or about 0.001-400 µg/ml, or about 0.001-300 µg/ml, or about 0.001-200 µg/ml, or about 0.001-150 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In another specific embodiment, the liquid rehydration composition comprises about 0.1-450 µg/ml, or about 0.1-400 µg/ml, or about 0.1-300 µg/ml, or about 0.1-200 µg/ml, or about 0.1-150 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In another specific embodiment, the liquid rehydration composition comprises about 1-450 µg/ml, or about 1-400 µg/ml, or about 1-300 µg/ml, or about 1-200 µg/ml, or about 1-150 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more

specifically, fucoidan. In yet another specific embodiment, the liquid rehydration composition comprises about 0.001-10 µg/ml, or about 0.1-100 µg/ml, or about 0.1-10 µg/ml, or about 1-100 µg/ml, or about 10-100 µg/ml, or about 10-150 µg/ml, or about 0.5-150 µg/ml of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan.

[0046] If the rehydration composition is to be reconstituted from a powder, the powder rehydration composition may comprise at least about 0.00001 wt %, or at least about 0.0001 wt %, or at least about 0.001 wt %, or at least about 0.01 wt %, or about 0.00001-0.5 wt % of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In a specific embodiment of the invention, the powder rehydration composition comprises about 0.00001 – 0.5 wt %, or about 0.0001-0.5 wt %, or about 0.001-0.5 wt %, or about 0.01-0.5 wt % of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In a specific embodiment of the invention, the powder rehydration composition comprises about 0.00001 – 0.4 wt %, or about 0.0001-0.4 wt %, or about 0.001-0.4 wt %, or about 0.01-0.4 wt % of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In a specific embodiment of the invention, the powder rehydration composition comprises about 0.00001 – 0.3 wt %, or about 0.0001-0.3 wt %, or about 0.001-0.3 wt %, or about 0.01-0.3 wt % of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In a specific embodiment of the invention, the powder rehydration composition comprises about 0.00001 – 0.2 wt %, or about 0.0001-0.2 wt %, or about 0.001-0.2 wt %, or about 0.01-0.2 wt % of the marine algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan. In another specific embodiment, the powder rehydration composition comprises about 0.0001-0.1 wt %, or about 0.0001-0.1 wt %, or about 0.001-0.1 wt %, or about 0.01-0.1 wt % of the marine

algae polysaccharide, or, more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan.

[0047] In certain embodiments of the invention, the liquid rehydration composition, reconstituted from a powder or manufactured as a ready-to-drink product, is an acidic liquid rehydration composition comprising at least one acid. In embodiments of the invention, the at least one acid comprises malic acid, phosphoric acid, and/or citric acid. In one embodiment, the at least one acid is citric acid. In one embodiment, the composition has a pH of less than about 6, or less than about 5, or less than about 4, or less than about 3, or about 3-6, or about 3-4. The at least one acid is included in the liquid rehydration composition in an amount sufficient to provide the desired pH and flavor profile of the composition. In embodiments of the invention, the rehydration composition comprises at least about 0.05 wt %, or about 0.05-5 wt %, or about 0.05-1.5 wt %, or about 0.05-2 wt %, or about 0.05-4 wt % of the at least one acid, or, specifically, of citric acid.

[0048] In embodiments of the invention, the at least one electrolyte comprises sodium, potassium, chloride, or a combination of two or more thereof.

[0049] In embodiments of the invention, the liquid rehydration composition, reconstituted from a powder or manufactured as a ready-to-drink product, generally comprises water and the electrolytes sodium, potassium, and chloride in amounts suitable for rehydration, including for purposes of preventing or treating dehydration. The relative amounts of these electrolytes also help to maintain (or reestablish) proper electrolyte balance within the body. Electrolyte imbalances, particularly of sodium, chloride, and potassium, can lead to life threatening situations, and these electrolytes can be lost through perspiration or as a result of diarrhea, vomiting, or other illness or medical condition.

[0050] In one embodiment, the rehydration composition comprises about 35 to about 45 mEq/L of sodium. In other embodiments, the rehydration composition comprises about 25 – 75 mEq/L, about 30 – 60 mEq/L, about 35 – 60 mEq/L, or about 40 – 50 mEq/L of sodium.

[0051] Sodium can be provided by a variety of sources, including one or more of sodium chloride, sodium phosphate, sodium citrate, sodium carbonate, sodium bicarbonate, sodium hydroxide, sodium selenate, and combinations thereof. In some embodiments, sodium ions are provided by a combination of sodium chloride and sodium citrate, which also provide chloride and citrate ions, respectively. Citrate (e.g., as sodium citrate and/or potassium citrate) also acts as a buffering agent, which helps maintain the desired pH of the composition.

[0052] In one embodiment, the rehydration composition comprises about 10 to about 20 mEq/L of potassium. In other embodiments, the rehydration composition is formulated to have about 15 – 40 mEq/L, or about 15 – 25 mEq/L, or about 20 – 40 mEq/L, or about 20 – 30 mEq/L of potassium.

[0053] Potassium can be provided by a variety of sources, including one or more of potassium chloride, potassium phosphate, potassium citrate, potassium carbonate, potassium bicarbonate, potassium hydroxide, acesulfame potassium, and combinations thereof. In some particular embodiments, potassium ions are provided by potassium citrate.

[0054] In one embodiment, the rehydration composition comprises about 30 to about 35 mEq/L of chloride. In other embodiments, the rehydration composition is formulated to have about 20 – 55 mEq/L, or about 30 – 50 mEq/L, or about 35 – 45 mEq/L of chloride.

[0055] Chloride can be provided by a variety of sources, including one or more of: sodium chloride, potassium chloride, calcium chloride, magnesium chloride, and combinations thereof. In some embodiments, chloride ions are provided by one or more of the same sources used to provide all or a portion of the sodium and potassium. Thus, in some particular embodiments, the chloride ions are provided by sodium chloride (which will also provide at least a portion of the sodium ions in the composition).

[0056] In a specific embodiment of the invention, the rehydration composition comprises about 35 to about 45 mEq/L of sodium, about 10 to about 20 mEq/L of potassium, and about 30 to about 35 mEq/L of chloride.

[0057] In another specific embodiment, the rehydration composition comprises at least one carbohydrate. In another specific embodiment, the rehydration composition comprises one or more carbohydrates comprising fiber, including, but not limited to oat fiber, soy fiber, and/or corn fiber, human milk oligosaccharides (HMOs), maltodextrin, corn syrup, sucralose, dextrose, fructooligosaccharides, glucose, glucose polymers, sucrose, fructose, fructose polymers, lactose, maltose, amylose glycogen, galactose, galactooligosaccharides, inulin, or a combination of two or more thereof.

[0058] In one specific embodiment, the rehydration composition comprises dextrose. Embodiments of the invention may include dextrose in an amount sufficient to provide rapid hydration, improve sodium absorption, and provide necessary calories. However, too much dextrose can slow the absorption of sodium and water or even exacerbate dehydration by pulling water out of the bloodstream. In addition, lower amounts of dextrose or other carbohydrates may provide nutritional benefits, as well as improved patient or consumer acceptance (in part, because dextrose increases the caloric and sugar content of the beverage). In certain embodiments, the rehydration composition includes sufficient dextrose to provide a molar ratio of dextrose to sodium of between about 1:1 to about 3:1, between about 2:1 to about 3:1, or between about 2:1 and about 2.5:1.

[0059] In certain embodiments, rehydration compositions include up to 225 mmol/L of dextrose. Other embodiments include between about 25 mmol/L and about 225 mmol/L, or between about 30 mmol/L and about 170 mmol/L, or between about 35 mmol/L and about 150 mmol/L, or between about 70 mmol/L and about 140 mmol/L of dextrose.

[0060] Some embodiments of the rehydration compositions include one or more sweeteners in order to improve the flavor profile of the composition. The presence of one or more sweeteners is also beneficial in that the sweeteners allow for reduced amounts of dextrose and other sugars while maintaining an acceptable flavor profile. The sweeteners may be natural and/or artificial. Suitable artificial sweeteners include saccharin, nutrasweet, sucralose,

aspartame, acesulfame-K (ace-K), and the like. When artificial sweeteners are used, the concentration of the artificial sweetener(s) can be from about 0.01 to about 0.5 g/L. In one embodiment, sweeteners may be added in the form of sucralose, stevia leaf extract, or the like.

[0061] Particular embodiments of the rehydration compositions include one or more natural sweeteners, particularly high intensity natural sweeteners. Suitable high intensity natural sweeteners include stevia leaf extract (commonly referred to as "stevia") and monk fruit extract (commonly referred to as "monk fruit"). Stevia and monk fruit are non-synthetic, high-intensity sweeteners that contribute no measurable amount of carbohydrates or calories and do not interfere with rehydration. Accordingly, the use of stevia and monk fruit allows the composition to have sufficient sweetness for palatability without altering the ratio of dextrose to sodium for optimal sodium and water absorption.

[0062] In some embodiments, rehydration compositions include between about 0.003 and about 0.04 wt. % of stevia, monk fruit, or a combination of stevia and monk fruit. In specific embodiments that include both stevia and monk fruit, the amount of stevia is equal to or greater than the amount of monk fruit in the formulation. For example, the ratio of stevia to monk fruit (by weight) can be between about 1:1 and about 3:1, between about 1.5:1 and 2.5:1, or about 2:1. In one embodiment, stevia may be added in the form of organic stevia leaf extract, or the like.

[0063] In certain embodiments, the rehydration composition comprises citrate. Citrate is useful in rehydration compositions for correcting acidosis associated with diarrhea and dehydration. The quantity of citrate varies widely. In certain exemplary embodiments, a source of citrate is present in an amount sufficient to provide from about 10 to about 50 mEq/L, about 15 to about 45 mEq/L, or about 20 to about 40 mEq/L of citrate. Citrate ions can be provided by a variety of sources, including one or more of: citric acid, citric esters that can be hydrolyzed into citric acid or a citrate ion, and citrate salts such as potassium citrate and sodium citrate. In some embodiments, citrate ions are provided by one or more of the same sources used to provide all

or a portion of the sodium and/or potassium. Thus, in some particular embodiments, the citrate ions are provided by sodium citrate (which will also provide at least a portion of the sodium ions in the composition) and potassium citrate (which will also provide at least a portion of the potassium ions in the composition).

[0064] Embodiments of the invention can also include one or more additional ingredients, including those commonly used in electrolyte beverages that do not adversely affect the rehydration effects of the beverage. Examples of additional ingredients include flavorants, preservatives, excipients, indigestible oligosaccharides, for example, galactooligosaccharides, amino acids, additional minerals (e.g., calcium), vitamins, dietary supplements, and combinations thereof.

[0065] Certain embodiments may also include zinc, as zinc can be important for, among other things, supporting the immune system (e.g., in individuals dehydrated as a result of illness). In one embodiment, zinc may be added in the form of zinc gluconate, zinc sulfate, zinc acetate, or the like. Embodiments of the invention may also include selenium. In one embodiment, selenium may be added in the form of sodium selenate, or the like.

[0066] Any of a variety of flavorants may be included to add or modify a flavor or to enhance the palatability of the composition. Flavorants can be natural or artificial. Suitable natural flavorants include citrus oils such as lemon, orange, lime and grapefruit oils, and fruit essences, including apple, pear, peach, berry, wildberry, date, blueberry, kiwi, strawberry, raspberry, cherry, plum, pineapple, and apricot. In one embodiment, flavorants may be added in the form of organic apple juice concentrate, organic flavor, natural flavor, natural and artificial flavors, natural flavor with other natural flavor, or the like.

[0067] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with dextrose, potassium citrate, salt, sodium citrate, citric acid, and zinc gluconate.

[0068] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with organic apple juice concentrate, organic dextrose, citric acid, organic flavor, potassium citrate, salt, sodium citrate, organic stevia leaf extract, and zinc gluconate.

[0069] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with natural flavor, citric acid, salt, potassium citrate, sodium citrate, sucralose, acesulfame potassium, and zinc gluconate.

[0070] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with dextrose, galactooligosaccharides, citric acid, potassium citrate, salt, natural and artificial flavors, sodium citrate, sucralose, acesulfame potassium, zinc gluconate, and sodium selenate.

[0071] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with dextrose, galactooligosaccharides, salt, citric acid, potassium citrate, sodium citrate, natural and artificial flavors, sucralose, acesulfame potassium, and zinc gluconate.

[0072] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with dextrose, galactooligosaccharides, salt, citric acid, potassium citrate, natural and artificial flavors, magnesium chloride, sodium citrate, acesulfame potassium, sucralose, zinc gluconate, and sodium selenate.

[0073] One specific embodiment of the invention comprises a liquid rehydration composition that comprises or consists essentially of water, marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, together with dextrose, galactooligosaccharides, salt, potassium citrate, citric acid, potassium phosphate, natural flavor with other natural flavors, magnesium chloride, sodium citrate, sucralose, and acesulfame potassium.

[0074] The rehydration compositions may be formed using any techniques known in the art. The marine algae polysaccharide may be added at any time as desired in the process.

[0075] In embodiments of the invention, the rehydration composition may be orally consumed by a subject for rehydration. The rehydration composition may be orally consumed once in order to rehydrate a subject, or may be consumed on a continuing basis to rehydrate and/or prevent dehydration of a subject. In a specific embodiment, the rehydration composition may be orally consumed at least once daily or multiple times daily for a period of at least about 1 week, at least about 2 weeks, at least about 3 weeks, or at least about 4 weeks.

[0076] For example, a rehydration composition comprising about 0.1-100 µg/ml, or about 10-100 µg/ml of marine algae polysaccharide, or more specifically, brown marine algae polysaccharide, or, more specifically, fucoidan, is administered to a subject to rehydrate the subject following a period of exercise or other activity which causes or risks dehydration. In a specific embodiment, such a rehydration composition is administered to the subject in a serving size of about 100-500 ml, or about 200-300 ml, or about 237 ml, or about 360 ml. Such a rehydration composition can also be administered at least once daily for a period of at least about one week to rehydrate an individual in a serving size of about 100-500 ml, or about 200-300 ml, or about 237 ml, or about 360 ml.

[0077] In specific embodiments of the invention, rehydration of a subject comprises strengthening an intestinal barrier of the subject. Strengthening the intestinal barrier comprises increasing water absorption across the intestinal barrier, where there is less water loss out the

apical side of the intestinal barrier compared to previous rehydration compositions and methods. As less water is lost out the apical side of the intestinal barrier, more water can be transported to the basal side of the intestinal barrier and into the blood stream to rehydrate the subject. Because a greater amount or proportion of the orally administered rehydration composition enters the blood stream, the hydrating effect achieved by the compositions of the present disclosure is greater than conventional rehydration compositions and methods.

[0078] The following Examples demonstrate various embodiments of the invention.

EXAMPLES

[0079] **Example 1:** Liquid Rehydration Composition

[0080] This example describes exemplary liquid rehydration compositions according to the invention that were prepared and tested for rehydration benefits.

[0081] Two liquid rehydration compositions were prepared, Sample 1 and Sample 2. Both Sample compositions initially contained water, dextrose, potassium citrate, sodium chloride, sodium citrate, citric acid, and zinc gluconate ("initial compositions"). Using a model of intestinal epithelial cells, 500 μ L of these initial compositions were added to cultures of live human intestinal epithelial cells at time 0, represented in FIG. 1.

[0082] Also shown in FIG. 1, after ten minutes, 50 μ L of water was added to Sample 1 and 50 μ L of water containing an amount of fucoidan (.55 μ g) sufficient to bring the concentration of fucoidan in the total composition to a concentration of 1 μ g/mL was added to Sample 2. The fucoidan was derived from a *Fucus vesiculosus* brown algae.

[0083] Current (in micro angstroms per centimeter squared (μ A/cm²)) was measured across the intestinal epithelial barrier of the cultured cells in the presence of Samples 1 and 2, respectively, for a period of 80 minutes, as shown in FIG. 1. Measurements were taken at 3 second intervals in each of 6 replicate intestinal cultures per Sample with Standard Error of the Mean (SEM) shown at 5 minute intervals. Negative current indicates net water absorption with

more negative current indicating a more rapid rate of water absorption. These measurements show the rehydration benefits of Samples 1 and 2 in real time at a molecular level.

[0084] As shown, the data presented in FIG. 1 indicates that Sample 2 resulted in a larger negative current and for a longer period of time compared to Sample 1. As such, Sample 2, the rehydration composition with the addition of a very small amount of fucoidan, unexpectedly provided enhanced water absorption, and therefore enhanced rehydration benefits, compared to Sample 1. This shows the surprising results that brown marine algae polysaccharide such as fucoidan enhances water absorption in model intestinal epithelial cells.

[0085] **Example 2: Liquid Rehydration Composition**

[0086] This example describes additional exemplary liquid rehydration compositions according to the invention that were prepared and tested for rehydration benefits.

[0087] Two liquid rehydration compositions were prepared, Sample 3 and Sample 4. Both Sample compositions initially contained water, dextrose, potassium citrate, sodium chloride, sodium citrate, citric acid, and zinc gluconate ("initial compositions"). Using a model of intestinal epithelial cells, 500 μL of these initial compositions were added to cultures of live human intestinal epithelial cells at time 0, represented in FIG. 2.

[0088] Also shown in FIG. 2, after a few minutes, 50 μL of water was added to Sample 3 and 50 μL of water containing an amount of fucoidan (55 μg) sufficient to bring the concentration of fucoidan in the total composition to a concentration of 100 $\mu\text{g/mL}$ was added to Sample 4. The fucoidan in this Example was also derived from a *Fucus vesiculosus* brown algae. Note that the negative spike in current for Sample 4 at time 0 shown in Figure 2 is due to data normalization at the outset and should be ignored.

[0089] Current (in micro amperes per centimeter squared ($\mu\text{A/cm}^2$)) was measured across the intestinal epithelial barrier of the cultured cells in the presence of Samples 3 and 4, respectively, for a period of 70 minutes, as shown in FIG. 2 and described in Table 1 below. Measurements were taken at 3 second intervals in each of 6 replicate intestinal cultures per

Sample with Standard Error of the Mean (SEM) shown at 5 minute intervals. As in Example 1, negative current indicates net water absorption with more negative current indicating a more rapid rate of water absorption. These measurements show the rehydration benefits of Samples 3 and 4 in real time at a molecular level. These measurements are shown in Table 1 below.

Table 1: Current Measurements of Samples 3 and 4

Time (min)	Sample	mean ($\mu\text{A}/\text{cm}^2$)	SEM
0	Sample 3	133.7173588	49.61368
	Sample 4	0.237512946	0.047297
5	Sample 3	-4.551910762	1.11841
	Sample 4	-13.27346577	2.112408
10	Sample 3	-4.058006131	0.754564
	Sample 4	-12.53543601	2.061832
15	Sample 3	-4.068208107	0.750317
	Sample 4	-11.83598958	2.031931
20	Sample 3	-3.774561667	0.733769
	Sample 4	-11.17403869	2.017916
25	Sample 3	-3.458888786	0.724008
	Sample 4	-10.52354167	2.035215
30	Sample 3	-3.171631619	0.721551
	Sample 4	-9.9383125	2.018032
35	Sample 3	-2.873119369	0.718743
	Sample 4	-9.435623512	2.005672
40	Sample 3	-2.607394399	0.716766
	Sample 4	-8.91746875	2.002291
45	Sample 3	-2.337888399	0.715748
	Sample 4	-8.423872024	1.998579
50	Sample 3	-2.077168735	0.717688
	Sample 4	-7.99021131	1.997487
55	Sample 3	-1.837122685	0.724627
	Sample 4	-7.537941964	1.985501
60	Sample 3	-1.588333173	0.729047
	Sample 4	-7.1424375	1.981868
65	Sample 3	-1.360612226	0.73495
	Sample 4	-6.766626488	1.977897
70	Sample 3	-1.109581048	0.740098
	Sample 4	-6.356668155	1.991223

[0090] As shown, the data presented in Table 1 and FIG. 2 indicates that Sample 4 resulted in a larger negative current and for a longer period of time compared to Sample 3. This further shows the surprising results that brown marine algae polysaccharide such as fucoidan enhances water absorption in model intestinal epithelial cells.

[0091] Surprisingly, small amounts of fucoidan, 1 µg/ml added to Sample 2, and 100 µg/ml added to Sample 4, caused an unexpected increase in rate and duration of water absorption across the model epithelial cells compared to the rehydration compositions of Samples 1 and 3.

[0092] **Example 3: Inhibition of Moisture Uptake**

[0093] A major challenge in making powdered rehydration compositions containing one or more electrolytes is caking, i.e. the transformation of free-flowing powder into aggregates or “cakes”. Caking is driven by moisture uptake. When particles are exposed to high ambient relative humidity, e.g. during processing or storage, liquid bridges can form between the particles. When the humidity lowers, the liquid bridges solidify, converting a free-flowing powder into a solid cake that does not dissolve as readily in water and which is aesthetically undesirable.

[0094] Caking can become even more challenging in powdered rehydration compositions as the number of ingredients, e.g. electrolytes, carbohydrates, salts, sugars, vitamins, etc., is increased due to the phenomenon known as blend deliquescence. If the atmospheric humidity to which a powder is subjected can be kept below the deliquescence point of the individual crystalline ingredients in a powder, than caking can be prevented. However, when multiple crystalline ingredients are mixed, the deliquescence point of the blend has been found to be lower than that of each of the individual crystalline ingredients alone. This phenomenon is known as blend deliquescence.

[0095] It is common to add an anti-caking agent to powdered compositions in order to prevent caking. Commonly used anti-caking agents include silicon dioxide, calcium silicate, magnesium silicate, talc, calcium carbonate, magnesium stearate, and the like.

[0096] This example describes additional exemplary powdered rehydration compositions that were tested for moisture uptake and by which it was found that the addition of small amounts of fucoidan reduced moisture uptake in the powder over time.

[0097] A number of powder compositions containing different amounts of fucoidan were prepared. The base of each composition was identical and contained dextrose, citric acid, fructooligosaccharides, potassium citrate, sodium chloride, sodium citrate dehydrate, acesulfame potassium, sucralose, calcium silicate, and flavoring agents. To the base composition was added an amount of *Undaria pinnatifida* (a species of brown seaweed) extract that contained approximately 87% fucoidan. Three test compositions were prepared, a first containing 0.07 wt.% fucoidan, a second containing 0.14 wt.% fucoidan, and a third containing 0.28 wt.% fucoidan. The base composition (containing no fucoidan) was used as a control.

[0098] The three test compositions and the control were then stored under an atmosphere having 75% relative humidity for a period of 70 days. Samples were tested for water uptake at various points throughout the 70 day storage. The results are shown in Figure 3.

[0099] As shown in Figure 3, all three test samples surprisingly demonstrated a statistically significant reduction in water uptake relative to the control. At the full 70 day time period, for example, the test sample containing 0.07 wt.% fucoidan had about 18% less water uptake than the control, the test sample containing 0.14 wt.% fucoidan had about 21% less water uptake than the control, and the test sample containing 0.28 wt.% fucoidan had about 24% less water uptake than the control. Additional testing showed that compositions containing fucoidan in significantly higher amounts had no effect, although it should be noted that that testing was only performed for a period of 25 days and at a lower humidity atmosphere (68.9% relative humidity) than the testing described above.

[0100] Due to the known relationship between moisture uptake and caking, the reduction in moisture uptake brought about by the addition of small amounts of fucoidan, as demonstrated by this testing, is expected to reduce caking of a powder rehydration composition according to

the present disclosure and subsequent challenges with dissolution by consumers, thereby resulting in a powder composition having improved storage and/or flow properties.

[0101] In summary, the present invention provides improved rehydration compositions and methods. Such compositions and methods allow for large-scale commercial production of rehydration compositions with improved rehydration benefits.

[0102] The specific embodiments and examples described herein are exemplary only and are not limiting to the invention defined in the claims. Additionally, while the present invention has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, such descriptions are not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the invention, in its broader aspects, is not limited to the specific details, the representative compositions and processes, or illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the general inventive concept.

Claims

What is claimed is:

1. A rehydration composition comprising water, at least one electrolyte, and a marine algae polysaccharide.
2. The rehydration composition of claim 1, wherein the marine algae polysaccharide comprises a brown marine algae polysaccharide.
3. The rehydration composition of claim 1 or 2, wherein the rehydration composition comprises about 0.1 to about 10 µg/ml of marine algae polysaccharide.
4. The rehydration composition of claim 1 or 2, wherein the rehydration composition comprises about 10 to about 150 µg/ml, optionally about 10-100 µg/ml, of marine algae polysaccharide.
5. The rehydration composition of any preceding claim, wherein the marine algae polysaccharide comprises fucoidan.
6. A rehydration composition comprising water, at least one electrolyte, and fucoidan.
7. The rehydration composition of claim 5 or 6, wherein the rehydration composition comprises about 0.1 to about 300 µg/ml, optionally, optionally about 0.5 to about 300 µg/ml, optionally about 0.5 to about 150 µg/ml, optionally about 1 to about 150 µg/ml, optionally about 10-100 µg/ml, of fucoidan.

8. The rehydration composition of any one of the preceding claims, further comprising at least one acid and wherein the composition has a pH of less than 6.
9. The rehydration composition of any one of the preceding claims, wherein the composition is heat sterilized.
10. The rehydration composition of any one of the preceding claims, wherein the electrolyte comprises sodium, potassium, chloride, or a combination of two or more thereof.
11. The rehydration composition of any one of the preceding claims, wherein the rehydration composition comprises about 25 to about 75 mEq/L of sodium.
12. The rehydration composition of any one of the preceding claims, wherein the rehydration composition comprises about 15 to about 40 mEq/L of potassium.
13. The rehydration composition of any one of the preceding claims, wherein the rehydration composition comprises about 20 to about 55 mEq/L of chloride.
14. The rehydration composition of any one of the preceding claims, further comprising zinc.
15. The rehydration composition of any one of the preceding claims, further comprising selenium.
16. The rehydration composition of any one of the preceding claims, further comprising one or more sweeteners.

17. The rehydration composition of any one of the preceding claims, wherein the rehydration composition comprises at least one carbohydrate.
18. The rehydration composition of any one of the preceding claims, wherein the rehydration composition comprises one or more carbohydrates comprising fiber, human milk oligosaccharides (HMOs), maltodextrin, corn syrup, sucralose, dextrose, fructooligosaccharides, glucose, glucose polymers, sucrose, fructose, fructose polymers, lactose, maltose, amylose glycogen, galactose, galactooligosaccharides, inulin, or a combination of two or more thereof.
19. A powder for forming a rehydration composition according to any one of claims 1-18 by addition of water.
20. The powder for forming a rehydration composition of claim 19, in which the powder comprises about 0.00001 wt % to about 0.5 wt % of marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan.
21. The powder for forming a rehydration composition according to claim 19, the powder comprising about 0.00001 wt % to about 0.2 wt % of marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan.
22. The rehydration composition or powder for forming a rehydration composition of any preceding claim, wherein the fucoidan is non-hydrolyzed.
23. The rehydration composition or powder for forming a rehydration composition of any preceding claim, wherein the marine algae polysaccharide, optionally brown marine

algae polysaccharide, optionally fucoidan is present in an effective amount to provide the rehydration composition with an improved hydrating effect.

24. The rehydration composition or powder for forming a rehydration composition of any preceding claim, wherein the marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan is present in an effective amount to increase an amount of water and electrolyte(s) that enters a blood stream of a subject, the rate at which water and electrolyte(s) enters a blood stream of a subject, or both, when the rehydration composition is consumed orally.
25. The rehydration composition or powder for forming a rehydration composition of any preceding claim, wherein the rehydration composition is configured to provide an improved hydrating effect compared to an identical rehydration composition but without the marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan.
26. The rehydration composition or powder for forming a rehydration composition of any preceding claim, wherein the rehydration composition is configured to increase an amount of water and electrolyte(s) that enters a blood stream of a subject, the rate at which water and electrolyte(s) enters a blood stream of a subject, or both when the rehydration composition is consumed orally.
27. A method of rehydrating a subject, comprising orally administering the rehydration composition according to any one of claims 1-26 to the subject.
28. The method of claim 27, wherein the subject is a pediatric subject.

29. The method of claim 27, wherein the subject is recovering from exercise.
30. The method of any one of claims 27 to 29, wherein the marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan improves the rehydrating effect of the composition.
31. The method of any one of claims 27 to 30, wherein an amount of water and electrolyte(s) that enters a blood stream of a subject, the rate at which water and electrolyte(s) enters a blood stream of a subject, or both is increased compared with administration of the same amount of an identical rehydration composition but without the marine algae polysaccharide, optionally brown marine algae polysaccharide, optionally fucoidan.
32. Use of a marine algae polysaccharide, optionally a brown marine algae polysaccharide, optionally fucoidan, to improve the hydrating effect of a rehydration composition comprising water and at least one electrolyte.
33. The use of claim 32, wherein the marine algae polysaccharide, optionally a brown marine algae polysaccharide, optionally fucoidan, is present in the rehydration composition in an amount between about 0.1 and about 300 µg/ml, optionally between about 0.1 and about 200 µg/ml, optionally between about 0.1 and about 150 µg/ml, optionally between about 0.1 and about 100 µg/ml.
34. The use of any one of claims 32 and 33 wherein the marine algae polysaccharide is fucoidan.
35. The use of claim 34, wherein the fucoidan is non-hydrolyzed.