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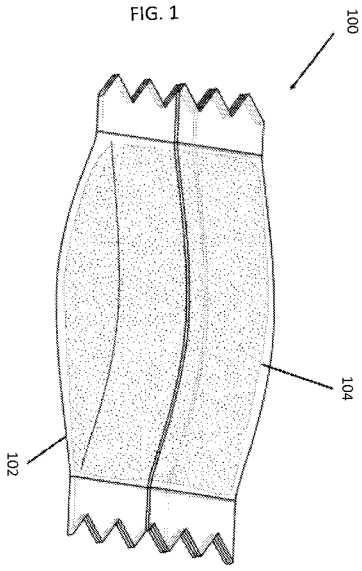
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(54) Title: POUCHED PRODUCT COMPRISING DISSOLVABLE COMPOSITION

(57) Abstract: A pouched product including an outer water-permeable pouch defining a cavity and a composition configured for oral use situated within the cavity is provided. The composition is at least partially orally dissolvable, and includes one or more dissolvable fillers in an amount of at least about 45% by weight, based on the total weight of the composition; a humectant in an amount up to about 25% by weight, based on the total weight of the composition; and at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant.

FIG. 1



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POUCHED PRODUCT COMPRISING DISSOLVABLE COMPOSITION

FIELD OF THE DISCLOSURE

The present disclosure relates to pouched products containing compositions intended for human use. The products are configured for oral use and deliver substances such as flavors and/or active ingredients during use. Such products may include tobacco or a product derived from tobacco, or may be tobacco-free alternatives.

BACKGROUND

Tobacco may be enjoyed in a so-called "smokeless" form. Particularly popular smokeless tobacco products are employed by inserting some form of processed tobacco or tobacco-containing formulation into the mouth of the user. Conventional formats for such smokeless tobacco products include moist snuff, snus, and chewing tobacco, which are typically formed almost entirely of particulate, granular, or shredded tobacco, and which are either portioned by the user or presented to the user in individual portions, such as in single-use pouches or sachets. Other traditional forms of smokeless products include compressed or agglomerated forms, such as plugs, tablets, or pellets. Alternative product formats, such as tobacco-containing gums and mixtures of tobacco with other plant materials, are also known. See for example, the types of smokeless tobacco formulations, ingredients, and processing methodologies set forth in US Pat. Nos. 1,376,586 to Schwartz; 4,513,756 to Pittman et al.; 4,528,993 to Sensabaugh, Jr. et al.; 4,624,269 to Story et al.; 4,991,599 to Tibbetts; 4,987,907 to Townsend; 5,092,352 to Sprinkle, III et al.; 5,387,416 to White et al.; 6,668,839 to Williams; 6,834,654 to Williams; 6,953,040 to Atchley et al.; 7,032,601 to Atchley et al.; and 7,694,686 to Atchley et al.; US Pat. Pub. Nos. 2004/0020503 to Williams; 2005/0115580 to Quinter et al.; 2006/0191548 to Strickland et al.; 2007/0062549 to Holton, Jr. et al.; 2007/0186941 to Holton, Jr. et al.; 2007/0186942 to Strickland et al.; 2008/0029110 to Dube et al.; 2008/0029116 to Robinson et al.; 2008/0173317 to Robinson et al.; 2008/0209586 to Neilsen et al.; 2009/0065013 to Essen et al.; and 2010/0282267 to Atchley, as well as WO2004/095959 to Arnarp et al., each of which is incorporated herein by reference.

Smokeless tobacco product configurations that combine tobacco material with various binders and fillers have been proposed more recently, with example product formats including lozenges, pastilles, gels, extruded forms, and the like. See, for example, the types of products described in US Patent App. Pub. Nos. 2008/0196730 to Engstrom et al.; 2008/0305216 to Crawford et al.; 2009/0293889 to Kumar et al.; 2010/0291245 to Gao et al; 2011/0139164 to Mua et al.; 2012/0037175 to Cantrell et al.; 2012/0055494 to Hunt et al.; 2012/0138073 to Cantrell et al.; 2012/0138074 to Cantrell et al.; 2013/0074855 to Holton, Jr.; 2013/0074856 to Holton, Jr.; 2013/0152953 to Mua et al.; 2013/0274296 to Jackson et al.; 2015/0068545 to Moldoveanu et al.;

2015/0101627 to Marshall et al.; and 2015/0230515 to Lampe et al., each of which is incorporated herein by reference. Oral products in similar formats and which are free of tobacco have also been proposed.

There is a continuing need in the art to develop product formats for oral products that enhance the sensory experience of the consumer.

BRIEF SUMMARY

The present disclosure generally provides a pouched product comprising an outer water-permeable pouch defining a cavity and a composition configured for oral use situated within the cavity, wherein the composition is at least partially dissolvable, the composition comprising: one or more dissolvable fillers in an amount of at least about 45% by weight, based on the total weight of the composition; a humectant in an amount up to about 25% by weight, based on the total weight of the composition; and at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant.

In some embodiments, the composition is at least about 50% orally dissolvable on a weight basis. In some embodiments, from about 95% to about 100% of the composition by weight is orally dissolvable.

In some embodiments, the one or more dissolvable fillers is selected from the group consisting sugars, sugar alcohols, soluble starches, soluble fibers, and combinations thereof. In some embodiments, the one or more dissolvable fillers comprise a sugar alcohol. In some embodiments, the sugar alcohol is isomalt. In some embodiments, the one or more dissolvable fillers further comprise maltodextrin.

In some embodiments, the humectant is present in an amount from about 15 about 20% by weight, based on the total weight of the composition. In some embodiments, the humectant is glycerin, propylene glycol, or a mixture thereof.

In some embodiments, the composition further comprises at least one sweetener.

In some embodiments, the composition is in particulate form, granulated form, or in the form of one or more pellets or tablets.

In some embodiments, the one or more dissolvable fillers comprise a sugar alcohol and maltodextrin, and optionally, wherein the composition further comprises microcrystalline cellulose in an amount up to about 40% by weight of the composition.

In some embodiments, the composition is in the form of beads, the composition comprising a sugar alcohol in an amount from about 67% to about 78% by weight, based on the total weight of the composition, and glycerin in an amount from about 16% to about 20% by weight, based on the total weight of the composition.

In some embodiments, the sugar alcohol is isomalt.

In some embodiments, the composition further comprises microcrystalline cellulose in an amount of up to about 5% by weight of the composition.

In some embodiments, at least a portion of the beads are coated with a release modifying agent selected from the group consisting of lipids, waxes, cellulose derivatives, binders, and combinations thereof.

In some embodiments, the pouched product comprises a mixture of beads having different dissolution rates.

In some embodiments, the pouched product further comprises microcrystalline cellulose in the form of a physical mixture with the beads.

In some embodiments, the at least one active ingredient is selected from the group consisting of botanical materials, stimulants, amino acids, vitamins, antioxidants, cannabinoids, cannabimimetics, terpenes, pharmaceutical agents, and combinations thereof. In some embodiments, the at least one active ingredient comprises a nicotine component. In some embodiments, the nicotine component comprises resin-bound nicotine. In some embodiments, the nicotine component is resin-bound nicotine.

In some embodiments, the composition further comprises one or more organic acids, an alkali metal salt of the one or more organic acids, or both.

In some embodiments, the one or more organic acids or alkali metal salt thereof is present in the composition in an amount by weight of from about 0.1 to about 10%, or from about 0.1 to about 0.5%, based on the total weight of the composition.

In some embodiments, the one or more organic acids comprises citric acid, malic acid, tartaric acid, octanoic acid, benzoic acid, a toluic acid, salicylic acid, or a combination thereof. In some embodiments, the one or more organic acids comprises benzoic acid. In some embodiments, at least a portion of the organic acid, the alkali metal salt of the organic acid, or both are associated with at least a portion of the nicotine component in the form of an ion pair.

In some embodiments, the outer water-permeable pouch is biodegradable. In some embodiments, the outer water-permeable pouch is dissolvable.

The disclosure includes, without limitations, the following embodiments.

Embodiment 1: A pouched product comprising an outer water-permeable pouch defining a cavity and a composition configured for oral use situated within the cavity, wherein the composition is at least partially dissolvable, the composition comprising: one or more dissolvable fillers in an amount of at least about 45% by weight, based on the total weight of the composition; a humectant in an amount up to about 25% by weight, based on the total weight of the composition; and at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant.

Embodiment 2: The pouched product of embodiment 1, wherein the composition is at least about 50% orally dissolvable on a weight basis.

Embodiment 3: The pouched product of embodiment 1 or 2, wherein from about 95% to about 100% of the composition by weight is orally dissolvable.

Embodiment 4: The pouched product of any one of embodiments 1-3, wherein the one or more dissolvable fillers is selected from the group consisting sugars, sugar alcohols, soluble starches, soluble fibers, and combinations thereof.

Embodiment 5: The pouched product of any one of claims 1-4, wherein the one or more dissolvable fillers comprise a sugar alcohol.

Embodiment 6: The pouched product of embodiment 5, wherein the sugar alcohol is isomalt.

Embodiment 7: The pouched product of embodiment 5 or 6, wherein the one or more dissolvable fillers further comprise maltodextrin.

Embodiment 8: The pouched product of any one of embodiments 1-7, wherein the humectant is present in an amount from about 15 about 20% by weight, based on the total weight of the composition.

Embodiment 9: The pouched product of any one of embodiments 1-8, wherein the humectant is glycerin, propylene glycol, or a mixture thereof.

Embodiment 10: The pouched product of any one of embodiments 1-9, wherein the composition further comprises at least one sweetener.

Embodiment 11: The pouched product of embodiment 1, wherein the composition is in particulate form, granulated form, or in the form of one or more pellets or tablets.

Embodiment 12: The pouched product of embodiment 11, wherein the one or more dissolvable fillers comprise a sugar alcohol and maltodextrin, and optionally, wherein the composition further comprises microcrystalline cellulose in an amount up to about 40% by weight of the composition.

Embodiment 13: The pouched product of embodiment 1, wherein the composition is in the form of beads, the composition comprising a sugar alcohol in an amount of at least 45% or more, such as from about 67% to about 78% by weight, based on the total weight of the composition, and glycerin in an amount of at least 10% or more, such as from about 16% to about 20% by weight, based on the total weight of the composition.

Embodiment 14: The pouched product of embodiment 13, wherein the sugar alcohol is isomalt.

Embodiment 15: The pouched product of embodiment 13 or 14, wherein the composition further comprises microcrystalline cellulose in an amount of up to about 5% by weight of the composition.

Embodiment 16: The pouched product of any one of embodiments 13-15, wherein at least a portion of the beads are coated with a release modifying agent selected from the group consisting of lipids, waxes, cellulose derivatives, binders, and combinations thereof.

Embodiment 17: The pouched product of any one of embodiments 13-16, wherein the pouched product comprises a mixture of beads having different dissolution rates.

Embodiment 18: The pouched product of any one of embodiments 13-17, further comprising microcrystalline cellulose in the form of a physical mixture with the beads.

Embodiment 19: The pouched product of any one of embodiments 1-18, wherein the at least one active ingredient is selected from the group consisting of botanical materials, stimulants, amino acids, vitamins, antioxidants, cannabinoids, cannabimimetics, terpenes, pharmaceutical agents, and combinations thereof.

Embodiment 20: The pouched product of any one of embodiments 1-19, wherein the at least one active ingredient comprises a nicotine component.Embodiment 21: The pouched product of embodiment 20, wherein the nicotine component comprises resin-bound nicotine.

Embodiment 22: The pouched product of any one of embodiments 1-21, wherein the composition further comprises one or more organic acids, an alkali metal salt of the one or more organic acids, or both.

Embodiment 23: The pouched product of embodiment 23, wherein the one or more organic acids or alkali metal salt thereof is present in the composition in an amount by weight of from about 0.1 to about 10%, or from about 0.1 to about 0.5%, based on the total weight of the composition.

Embodiment 24: The pouched product of embodiment 22 or 23, wherein the one or more organic acids comprises citric acid, malic acid, tartaric acid, octanoic acid, benzoic acid, a toluic acid, salicylic acid, or a combination thereof.

Embodiment 25: The pouched product of any one of embodiments 22-24, wherein the one or more organic acids comprises benzoic acid.

Embodiment 26: The pouched product of any one of embodiments 1-25, wherein the outer water-permeable pouch is biodegradable.

Embodiment 27: The pouched product of any one of embodiments 1-26, wherein the outer water-permeable pouch is dissolvable.

These and other features, aspects, and advantages of the disclosure will be apparent from a reading of the following detailed description together with the accompanying drawings, which are briefly described below. The invention includes any combination of two, three, four, or more of the above-noted embodiments as well as combinations of any two, three, four, or more features or elements set forth in this disclosure, regardless of whether such features or elements are expressly combined in a specific embodiment description herein. This disclosure is intended to be read holistically such that any separable features or elements of the disclosed invention, in any of its

various aspects and embodiments, should be viewed as intended to be combinable unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus described aspects of the disclosure in the foregoing general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale. The drawings are exemplary only, and should not be construed as limiting the disclosure.

FIG. 1 is a perspective view of a pouched product according to an example embodiment of the present disclosure including a pouch at least partially filled with a composition of the present disclosure.

FIG. 2 is a perspective view of a pouched product according to an example embodiment of the present disclosure, taken across the length of the product, showing a pouch at least partially filled with a composition of the present disclosure.

FIG. 3 is another perspective view of a pouched product according to an example embodiment of the present disclosure, taken across the length of the product, showing a pouch at least partially filled with a composition of the present disclosure.

DETAILED DESCRIPTION

The present disclosure provides a composition configured for oral use enclosed in an outer water-permeable pouch. The composition is at least partially dissolvable and comprises a dissolvable filler in an amount of, for example, at least about 45% by weight, based on the total weight of the composition, a humectant in an amount of, for example, up to about 25% by weight, based on the total weight of the composition, and at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant. The present disclosure will now be described more fully hereinafter with reference to example embodiments thereof. These example embodiments are described so that this disclosure will be thorough and complete, and will fully convey the scope of the disclosure to those skilled in the art. Indeed, the disclosure may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements.

As used in this specification and the claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

The term "about" used throughout this specification is used to describe and account for small fluctuations. For example, the term "about" can refer to less than or equal to ±10%, such as less than or equal to ±5%, less than or equal to ±2%, less than or equal to ±1%, less than or equal to ±0.5%, less than or equal to ±0.2%, less than or equal to ±0.1% or less than or equal to ±0.05%. All numeric values herein are modified by the term "about," whether or not explicitly indicated. A value

modified by the term "about" of course includes the specific value. For instance, "about 5.0" must include 5.0.

Reference to "dry weight percent" or "dry weight basis" refers to weight on the basis of dry ingredients (i.e., all ingredients except water). Reference to "wet weight" refers to the weight of the composition including water. Unless otherwise indicated, reference to "weight percent" of a composition reflects the total wet weight of the composition (i.e., including water).

Composition

In certain embodiments, the dissolvable composition as described herein comprises a dissolvable filler in an amount of at least about 45% by weight, based on the total weight of the composition, a humectant in an amount up to about 25% by weight, based on the total weight of the composition, and at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant. In some embodiments, the composition may further comprise a sweetener, one or more organic acids, and various other additives. The relative amounts of the various components within the composition may vary, and typically are selected so as to provide the desired sensory and performance characteristics to the oral product. The example individual components of the composition are described herein below.

Filler

Compositions as described herein include at least one filler. Such fillers may fulfill multiple functions, such as enhancing certain organoleptic properties such as texture and mouthfeel, enhancing cohesiveness or compressibility of the product, and the like. Generally, the fillers are porous particulate materials and are cellulose-based. For example, suitable fillers are any non-tobacco plant material or derivative thereof, including cellulose materials derived from such sources. Examples of cellulosic non-tobacco plant material include cereal grains (e.g., maize, oat, barley, rye, buckwheat, and the like), sugar beet (e.g., FIBREX® brand filler available from International Fiber Corporation), bran fiber, and mixtures thereof. Non-limiting examples of derivatives of non-tobacco plant material include starches (e.g., from potato, wheat, rice, corn), natural cellulose, and modified cellulosic materials. Additional examples of potential fillers include maltodextrin, dextrose, lactose, mannitol, xylitol, and sorbitol. Combinations of fillers can also be used.

In some embodiments, the filler comprises a starch. The term "starch" as used herein may refer to pure starch from any source, modified starch, or starch derivatives. Starch is present, typically in granular form, in almost all green plants and in various types of plant tissues and organs (e.g., seeds, leaves, rhizomes, roots, tubers, shoots, fruits, grains, and stems). Starch can vary in composition, as well as in granular shape and size. Often, starch from different sources has different chemical and physical characteristics. A specific starch can be selected for inclusion in the product

based on the ability of the starch material to impart a specific organoleptic property to the product. Starches derived from various sources can be used. For example, major sources of starch include cereal grains (e.g., rice, wheat, and maize) and root vegetables (e.g., potatoes and cassava). Other examples of sources of starch include acorns, arrowroot, arracacha, bananas, barley, beans (e.g., favas, lentils, mung beans, peas, chickpeas), breadfruit, buckwheat, canna, chestnuts, colacasia, katakuri, kudzu, malanga, millet, oats, oca, Polynesian arrowroot, sago, sorghum, sweet potato, quinoa, rye, tapioca, taro, tobacco, water chestnuts, and yams.

Certain starches are modified starches. A modified starch has undergone one or more structural modifications, often designed to alter its high heat properties. Some starches have been developed by genetic modifications, and are considered to be "modified" starches. Other starches are obtained and subsequently modified. For example, modified starches can be starches that have been subjected to chemical reactions, such as esterification, etherification, oxidation, depolymerization (thinning) by acid catalysis or oxidation in the presence of base, bleaching, transglycosylation and depolymerization (e.g., dextrinization in the presence of a catalyst), cross-linking, enzyme treatment, acetylation, hydroxypropylation, and/or partial hydrolysis. Other starches are modified by heat treatments, such as pregelatinization, dextrinization, and/or cold water swelling processes. Certain modified starches include monostarch phosphate, distarch glycerol, distarch phosphate esterified with sodium trimetaphosphate, phosphate distarch phosphate, acetylated distarch phosphate, starch acetate esterified with acetic anhydride, starch acetate esterified with vinyl acetate, acetylated distarch adipate, acetylated distarch glycerol, hydroxypropyl starch, hydroxypropyl distarch glycerol, starch sodium octenyl succinate.

In some embodiments, the filler comprises a cellulosic material. In some embodiments, the cellulosic material is microcrystalline cellulose ("mcc"). The mcc may be synthetic or semi-synthetic, or it may be obtained entirely from natural celluloses. The mcc may be selected from the group consisting of AVICEL® grades PH-100, PH-102, PH-103, PH-105, PH-112, PH-113, PH-200, PH-300, PH-302, VIVACEL® grades 101, 102, 12, 20 and EMOCEL® grades 50M and 90M, and the like, and mixtures thereof. In some embodiments, the product comprises mcc. The quantity of mcc present in the product as described herein may vary according to the desired properties.

In some embodiments, the filler comprises a cellulose derivative, such as cellulose ethers (including carboxyalkyl ethers), meaning cellulose polymers with the hydrogen of one or more hydroxyl groups in the cellulose structure replaced with an alkyl, hydroxyalkyl, or aryl group. Non-limiting examples of such cellulose derivatives include methylcellulose, hydroxypropylcellulose ("HPC"), hydroxypropylmethylcellulose ("HPMC"), hydroxyethyl cellulose, and carboxymethylcellulose ("CMC"). Suitable cellulose ethers include hydroxypropylcellulose, such as Klucel H from Aqualon Co.; hydroxypropylmethylcellulose, such as Methocel K4MS from DuPont; hydroxyethylcellulose, such as Natrosol 250 MRCS from Aqualon Co.; methylcellulose, such as

Methocel A4M, K4M, and E15 from DuPont.; and sodium carboxymethylcellulose, such as CMC 7HF, CMC 7LF, and CMC 7H4F from Aqualon Co. In some embodiments, at least one filler is one or more cellulose ethers (e.g., a single cellulose ether or a combination of several cellulose ethers, such as two or three, for example). In some embodiments, the filler is a cellulose ether selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethyl cellulose, carboxymethylcellulose, and combinations thereof. In some embodiments, the at least one filler is carboxymethylcellulose.

Other suitable fillers include gums, for example, a natural gum. As used herein, a natural gum refers to polysaccharide materials of natural origin that have binding properties, and which are also useful as a thickening or gelling agents. Representative natural gums derived from plants, which are typically water soluble to some degree, include xanthan gum, guar gum, gum arabic, ghatti gum, gum tragacanth, karaya gum, locust bean gum, gellan gum, and combinations thereof.

In some embodiments, the filler comprises one or more sugar alcohols. Sugar alcohols are polyols derived from monosaccharides or disaccharides that have a partially or fully hydrogenated form. Sugar alcohols have, for example, about 4 to about 20 carbon atoms and include erythritol, arabitol, ribitol, isomalt, maltitol, dulcitol, iditol, mannitol, xylitol, lactitol, sorbitol, and combinations thereof (e.g., hydrogenated starch hydrolysates). In some embodiments, the filler comprises erythritol, isomalt, maltitol, mannitol, sorbitol, or a combination thereof. In some embodiments, filler is a combination of mannitol and maltodextrin. In some embodiments, the filler comprises isomalt. Isomalt is an equimolar mixture of two disaccharides, each composed of two sugars as follows: glucose and mannitol (α-D-glucopyranosido-1,6-mannitol); and glucose and sorbitol (α-D-glucopyranosido-1,6-sorbitol). In some embodiments, the filler comprises a mixture of glucose and starch-derived polysaccharides. One such suitable mixture of glucose and starch-derived polysaccharides is EMDEX®, available from JRS PHARMA LP, USA, 2981 Route 22, Patterson, NY 12563-2359. In some embodiments, the filler comprises EMDEX®.

In some embodiments, the filler is dissolvable. By "dissolvable" is meant that the filler is water soluble, such that the dissolvable filler is substantially or completely soluble in the saliva present in the mouth of a user of the composition. By "completely soluble" is meant that no residue of the dissolvable filler remains in solid form in the mouth of the user following a typical period of use of a product comprising the dissolvable filler. In some embodiments, the dissolvable filler comprises a soluble fiber, such as inulin or corn fiber. In some embodiments, the dissolvable filler comprises a soluble starch. In some embodiments, the soluble starch is maltodextrin. In some embodiments, the dissolvable filler comprises a sugar. In some embodiments, the dissolvable filler comprises a sugar alcohol. In some embodiments, dissolvable filler is a combination of isomalt and maltodextrin.

The amount of dissolvable filler can vary, but is typically greater than about 45%, and up to about 95% of the composition by weight, based on the total weight of the composition. A typical range of dissolvable filler within the composition can be from about 45 to about 95% by total weight of the composition, for example, from about 45, about 50, about 55, about 60, or about 65, to about 70, about 75, about 80, about 85, about 90, or about 95% by weight. It is to be understood that in embodiments where the composition comprises more than one dissolvable filler, the stated weight basis of the dissolvable filler reflects the total weight of the combination of dissolvable fillers, based on the total weight of the composition.

In some embodiments, the composition further comprises a filler which is not dissolvable, or is only partially dissolvable. The quantity of non-dissolvable or partially dissolvable filler which may be present may vary, but is typically less than about 40% by weight of the composition, such as from about 1 to about 40%, about 1 to about 20%, or from about 1 to about 5% by weight, based on the total weight of the composition. In some embodiments, the non-dissolvable filler is microcrystalline cellulose. In some embodiments, the composition further comprises microcrystalline cellulose in an amount up to about 5% by weight, based on the total weight of the composition. In some embodiments, the composition further comprises microcrystalline cellulose in an amount up to about 40% by weight, based on the total weight of the composition, such as from about 1 to about 40% by weight. Without wishing to be bound by theory, it is believed that inclusion of a partially or non-dissolvable filler such as microcrystalline cellulose may be advantageous for carrying a flavorant or active ingredient, and providing a more homogenous distribution of such throughout the product.

Humectants

In certain embodiments, one or more humectants may be employed in the composition. Examples of humectants include, but are not limited to, glycerin, propylene glycol, and the like. Where included, the humectant is typically provided in an amount sufficient to provide desired moisture attributes to the composition. Further, in some instances, the humectant may impart desirable flow characteristics to the composition for depositing in a mold, extruding the composition, and/or forming beads. In some instances, the humectant may aid in preventing particulate embodiments (e.g., powders) from forming airborne dusts, or from scorching during heat sealing of pouches. In some instances, the humectant may aid in in the formation of beads by extrusion, spheronization, rolling, and combinations thereof. In some embodiments, the humectant is propylene glycol. In some embodiments, the humectant is glycerin.

When present, a humectant will typically make up about 25% or less of the weight of the composition (e.g., from about 0.1 to about 25% by weight), for example, from about 0.1% to about 1% by weight, about 1% to about 5% by weight, about 5 to about 15% by weight, or about 15 to about 20% by weight, based on the total weight of the composition.

Binder

A binder (or combination of binders) may be employed in certain embodiments, in amounts sufficient to provide the desired physical attributes and physical integrity to the composition, and binders also often function as thickening or gelling agents. Typical binders can be organic or inorganic, or a combination thereof. Representative binders include cellulose derivatives (e.g., cellulose ethers), povidone, sodium alginate, starch-based binders, pectin, gums, carrageenan, pullulan, zein, and the like, and combinations thereof. In some embodiments, the binder comprises pectin or carrageenan or combinations thereof.

The amount of binder utilized in the composition can vary based on the binder and the desired composition properties, but is typically up to about 25% by weight, and certain embodiments are characterized by a binder content of at least about 0.1% by weight, such as about 0.5 to about 20% by weight, or about 1 to about 10% by weight, based on the total weight of the composition.

In one embodiment, the binder comprises a cellulose derivative. In certain embodiments, the cellulose derivative is a cellulose ether (including carboxyalkyl ethers), meaning a cellulose polymer with the hydrogen of one or more hydroxyl groups in the cellulose structure replaced with an alkyl, hydroxyalkyl, or aryl group. Non-limiting examples of such cellulose derivatives include methylcellulose, hydroxypropylcellulose ("HPC"), hydroxypropylmethylcellulose ("HPMC"), hydroxyethyl cellulose, and carboxymethylcellulose ("CMC"). In one embodiment, the cellulose derivative is one or more of methylcellulose, HPC, HPMC, hydroxyethyl cellulose, and CMC. In some embodiments, the cellulose derivative is HPC. In one embodiment, the cellulose derivative is a combination of HPC and HPMC. In some embodiments, the composition comprises from about 1 to about 5% by weight of HPC, for example, from about 1%, about 2%, or about 3%, to about 4%, or about 5% by weight of the composition.

In certain embodiments, the binder includes an alginate (e.g., sodium or ammonium alginate). When present, alginate binder materials are typically present in an amount of up to about 1% by weight, for example, from about 0.1, about 0.2, about 0.3, about 0.4, or about 0.5, to about 0.6, about 0.7, about 0.8, about 0.9, or about 1%, by weight, based on the total weight of the composition.

In certain embodiments, the binder includes an elastomeric polymer. Elastomeric polymers may include materials used in the manufacture of chewing gum, such as polyvinyl acetate or butadiene-styrene.

In certain embodiments, the binder includes a gum, for example, a natural gum. As used herein, a natural gum refers to polysaccharide materials of natural origin that have binding properties, and which are also useful as a thickening or gelling agents. Representative natural gums derived from plants, which are typically water soluble to some degree, include xanthan gum, guar gum, gum arabic, ghatti gum, gum tragacanth, karaya gum, locust bean gum, gellan gum, and combinations thereof. In certain embodiments, the binder comprises gum Arabic. When present, natural gum binder materials

are typically present in an amount of up to about 25% by weight, for example, from about 1%, about 2%, about 3%, about 4%, or about 5%, to about 10%, about 15%, about 20%, or about 25% by weight, based on the total weight of the composition.

In some embodiments, the composition comprises a binder which is coated on the surface of e.g., beads, tablets, or granular particles comprising the composition. Without wishing to be bound by theory, such coatings may alter the dissolution rate of components within the composition, or of the composition itself. Suitable binders for coating include, but are not limited to, cellulose derivatives and polymeric materials.

Active ingredient

In some embodiments, the composition as disclosed herein includes one or more active ingredients. As used herein, an "active ingredient" refers to one or more substances belonging to any of the following categories: API (active pharmaceutical substances), food additives, natural medicaments, and naturally occurring substances that can have an effect on humans. Example active ingredients include any ingredient known to impact one or more biological functions within the body, such as ingredients that furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or which affect the structure or any function of the body of humans (e.g., provide a stimulating action on the central nervous system, have an energizing effect, an antipyretic or analgesic action, or an otherwise useful effect on the body). In some embodiments, the active ingredient may be of the type generally referred to as dietary supplements, nutraceuticals, "phytochemicals" or "functional foods". These types of additives are sometimes defined in the art as encompassing substances typically available from naturally-occurring sources (e.g., botanical materials) that provide one or more advantageous biological effects (e.g., health promotion, disease prevention, or other medicinal properties), but are not classified or regulated as drugs.

Non-limiting examples of active ingredients include those falling in the categories of botanical ingredients (e.g., hemp, lavender, peppermint, eucalyptus, rooibos, fennel, cloves, chamomile, basil, rosemary, clove, citrus, ginger, cannabis, ginseng, maca, and tisanes), stimulants (e.g., caffeine or guarana), amino acids (e.g., taurine, theanine, phenylalanine, tyrosine, and tryptophan), vitamins (e.g., B6, B12, and C), antioxidants, nicotine components, pharmaceutical ingredients (e.g., nutraceutical and medicinal ingredients), cannabinoids (e.g., tetrahydrocannabinol (THC) or cannabidiol (CBD)) and/or melatonin.. Each of these categories is further described herein below. The particular choice of active ingredients will vary depending upon the desired flavor, texture, and desired characteristics of the particular product.

Furthermore, any of the aforementioned types of active ingredients may be encapsulated in the composition, the final product, or both to avoid chemical degradation or reduce strong taste of

these actives, including but not limited to caffeine, Vitamin A, and iron (Fe). Additionally, these encapsulated actives may need to be paired with an excipient in the composition to increase their solubility and/or bioavailability. Non-limiting examples of these excipients include beta-carotene, lycopene, Vitamin D, Vitamin E, Co-enzyme Q10, Vitamin K, and curcumin.

The particular percentages of active ingredients present will vary depending upon the desired characteristics of the particular product. Typically, an active ingredient or combination thereof is present in a total concentration of at least about 0.001% by weight of the composition, such as in a range from about 0.001% to about 20%. In some embodiments, the active ingredient or combination of active ingredients is present in a concentration from about 0.1% w/w to about 10% by weight, such as, e.g., from about 0.5% w/w to about 10%, from about 1% to about 10%, from about 1% to about 5% by weight, based on the total weight of the composition. In some embodiments, the active ingredient or combination of active ingredients is present in a concentration of from about 0.001%, about 0.01%, about 0.1% , or about 1%, up to about 20% by weight, such as, e.g., from about 0.001%, about 0.002%, about 0.003%, about 0.004%, about 0.005%, about 0.006%, about 0.007%, about 0.008%, about 0.009%, about 0.01%, about 0.02%, about 0.03%, about 0.04%, about 0.05%, about 0.06%, about 0.07%, about 0.08%, about 0.09%, about 0.1%, about 0.2%, about 0.3%, about 0.4%, about 0.5% about 0.6%, about 0.7%, about 0.8%, or about 0.9%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, about 10%, about 11%, about 12%, about 13%, about 14%, about 15%, about 16%, about 17%, about 18%, about 19%, or about 20% by weight, based on the total weight of the composition. Further suitable ranges for specific active ingredients are provided herein below.

Botanical

In some embodiments, the active ingredient comprises a botanical ingredient. As used herein, the term "botanical ingredient" or "botanical" refers to any plant material or fungal-derived material, including plant material in its natural form and plant material derived from natural plant materials, such as extracts or isolates from plant materials or treated plant materials (e.g., plant materials subjected to heat treatment, fermentation, bleaching, or other treatment processes capable of altering the physical and/or chemical nature of the material). For the purposes of the present disclosure, a "botanical" includes, but is not limited to, "herbal materials," which refer to seed-producing plants that do not develop persistent woody tissue and are often valued for their medicinal or sensory characteristics (e.g., teas or tisanes). Reference to botanical material as "non-tobacco" is intended to exclude tobacco materials (i.e., does not include any *Nicotiana* species).

When present, a botanical is typically at a concentration of from about 0.01% w/w to about 10% by weight, such as, e.g., from about 0.01% w/w, about 0.05%, about 0.1%, or about 0.5%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, or

about 10%, about 11%, about 12%, about 13%, about 14%, or about 15% by weight, based on the total weight of the composition.

The botanical materials useful in the present disclosure may comprise, without limitation, any of the compounds and sources set forth herein, including mixtures thereof. Certain botanical materials of this type are sometimes referred to as dietary supplements, nutraceuticals, "phytochemicals" or "functional foods." Certain botanicals, as the plant material or an extract thereof, have found use in traditional herbal medicine, and are described further herein. Non-limiting examples of botanicals or botanical-derived materials include ashwagandha, *Bacopa monniera,* baobab, basil, *Centella asiatica*, Chai-hu, chamomile, cherry blossom, chlorophyll, cinnamon, citrus, cloves, cocoa, cordyceps, curcumin, damiana, *Dorstenia arifolia*, *Dorstenia odorata*, essential oils, eucalyptus, fennel, *Galphimia glauca*, ginger, *Ginkgo biloba*, ginseng (e.g., *Panax ginseng*), green tea, *Griffonia simplicifolia*, guarana, hemp, hops, jasmine, *Kaempferia parviflora* (Thai ginseng), kava, lavender, lemon balm, lemongrass, licorice, lutein, maca, matcha, Nardostachys chinensis, oil-based extract of *Viola odorata*, peppermint, quercetin, resveratrol, *Rhizoma gastrodiae, Rhodiola, rooibos*, rose essential oil, rosemary, *Sceletium tortuosum*, Schisandra, Skullcap, spearmint extract, Spikenard, terpenes, tisanes, turmeric, *Turnera aphrodisiaca,* valerian, white mulberry, and *Yerba mate.* In some embodiments, the botanical material is in an encapsulated form.

Stimulants

In some embodiments, the active ingredient comprises one or more stimulants. As used herein, the term "stimulant" refers to a material that increases activity of the central nervous system and/or the body, for example, enhancing focus, cognition, vigor, mood, alertness, and the like. Non-limiting examples of stimulants include caffeine, theacrine, theobromine, and theophylline. Theacrine (1,3,7,9-tetramethyluric acid) is a purine alkaloid which is structurally related to caffeine, and possesses stimulant, analgesic, and anti-inflammatory effects. Present stimulants may be natural, naturally derived, or wholly synthetic. For example, certain botanical materials (guarana, tea, coffee, cocoa, and the like) may possess a stimulant effect by virtue of the presence of e.g., caffeine or related alkaloids, and accordingly are "natural" stimulants. By "naturally derived" is meant the stimulant (e.g., caffeine, theacrine) is in a purified form, outside its natural (e.g., botanical) matrix. For example, caffeine can be obtained by extraction and purification from botanical sources (e.g., tea). By "wholly synthetic", it is meant that the stimulant has been obtained by chemical synthesis. In some embodiments, the active ingredient comprises caffeine. In some embodiments, the caffeine is present in an encapsulated form. On example of an encapsulated caffeine is Vitashure®, available from Balchem Corp., 52 Sunrise Park Road, New Hampton, NY, 10958. In some embodiments, the active ingredient comprises theacrine. In some embodiments, the active ingredient comprises a combination of caffeine and theacrine.

When present, a stimulant or combination of stimulants (e.g., caffeine, theacrine, and combinations thereof) is typically at a concentration of from about 0.1% w/w to about 15% by weight, such as, e.g., from about 0.1% w/w, about 0.2%, about 0.3%, about 0.4%, about 0.5% about 0.6%, about 0.7%, about 0.8%, or about 0.9%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, about 10%, about 11%, about 12%, about 13%, about 14%, or about 15% by weight, based on the total weight of the composition.

Amino acids

In some embodiments, the active ingredient comprises an amino acid. As used herein, the term "amino acid" refers to an organic compound that contains amine ($-NH_2$) and carboxyl (-COOH) or sulfonic acid (SO_3H) functional groups, along with a side chain (R group), which is specific to each amino acid. Amino acids may be proteinogenic or non-proteinogenic. By "proteinogenic" is meant that the amino acid is one of the twenty naturally occurring amino acids found in proteins. The proteinogenic amino acids include alanine, arginine, asparagine, aspartic acid, cysteine, glutamine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, and valine. By "non-proteinogenic" is meant that either the amino acid is not found naturally in protein, or is not directly produced by cellular machinery (e.g., is the product of post-tranlational modification). Non-limiting examples of non-proteinogenic amino acids include gamma-aminobutyric acid (GABA), taurine (2-aminoethanesulfonic acid), theanine (L-γ-glutamylethylamide), hydroxyproline, and beta-alanine.

When present, an amino acid or combination of amino acids (e.g., taurine, theanine, and combinations thereof) is typically at a concentration of from about 0.1% w/w to about 15% by weight, such as, e.g., from about 0.1% w/w, about 0.2%, about 0.3%, about 0.4%, about 0.5% about 0.6%, about 0.7%, about 0.8%, or about 0.9%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, about 10%, about 11%, about 12%, about 13%, about 14%, or about 15% by weight, based on the total weight of the composition.

In some embodiments, the amino acid is taurine, theanine, phenylalanine, tyrosine, tryptophan, or a combination thereof. In some embodiments, the amino acid is taurine. In some embodiments, the active ingredient comprises a combination of taurine and caffeine. In some embodiments, the active ingredient comprises a combination of taurine, caffeine, and guarana. In some embodiments, the active ingredient comprises a combination of taurine, maca, and cordyceps. In some embodiments, the active ingredient comprises a combination of theanine and caffeine. In some embodiments, the active ingredient comprises a combination of theanine and caffeine. In some embodiments, the active ingredient comprises a combination of theanine and GABA. In some embodiments, the active ingredient comprises a combination of theanine, GABA, and lemon balm. In some embodiments, the active ingredient comprises a combination of caffeine, taurine, and Vitamin

C. In some embodiments, the active ingredient is a combination of caffeine, theanine, and ginseng. In some embodiments, the active ingredient comprises taurine.

Vitamins and Minerals

In some embodiments, the active ingredient comprises a vitamin or combination of vitamins. As used herein, the term "vitamin" refers to an organic molecule (or related set of molecules) that is an essential micronutrient needed for the proper functioning of metabolism in a mammal. There are thirteen vitamins required by human metabolism, which are: vitamin A (as all-trans-retinol, all-trans-retinyl-esters, as well as all-trans-beta-carotene and other provitamin A carotenoids), vitamin B1 (thiamine), vitamin B2 (riboflavin), vitamin B3 (niacin), vitamin B5 (pantothenic acid), vitamin B6 (pyridoxine), vitamin B7 (biotin), vitamin B9 (folic acid or folate), vitamin B12 (cobalamins), vitamin C (ascorbic acid), vitamin D (calciferols), vitamin E (tocopherols and tocotrienols), and vitamin K (quinones). In some embodiments, the active ingredient comprises vitamin C. In some embodiments, the active ingredient is a combination of vitamin C, caffeine, and taurine. In some embodiments, the active ingredient comprises one or more of vitamin B6 and B12. In some embodiments, the active ingredient comprises theanine and one or more of vitamin B6 and B12.

When present, a vitamin or combination of vitamins (e.g., vitamin B6, vitamin B12, vitamin E, vitamin C, or a combination thereof) is typically at a concentration of from about 0.01% w/w to about 1% by weight, such as, e.g., from about 0.01%, about 0.02%, about 0.03%, about 0.04%, about 0.05%, about 0.06%, about 0.07%, about 0.08%, about 0.09%, or about 0.1% w/w, to about 0.2%, about 0.3%, about 0.4%, about 0.5% about 0.6%, about 0.7%, about 0.8%, about 0.9%, or about 1% by weight, based on the total weight of the composition.

In some embodiments, the active ingredient comprises vitamin A. In some embodiments, the vitamin A is encapsulated. In some embodiments, the vitamin is vitamin B6, vitamin B12, vitamin E, vitamin C, or a combination thereof.

In some embodiments, the active ingredient comprises a mineral. As used herein, the term "mineral" refers to an inorganic molecule (or related set of molecules) that is an essential micronutrient needed for the proper functioning of various systems in a mammal. Non-limiting examples of minerals include iron, zinc, copper, selenium, chromium, cobalt, manganese, calcium, phosphorus, sulfur, magnesium, and the like. In some embodiments, the active ingredient comprises iron. Suitable sources of iron include, but are not limited to, ferrous salts such as ferrous sulfate and ferrous gluconate. In some embodiments, the iron is encapsulated.

In some embodiments, the active ingredient as described herein may be sensitive to degradation (e.g., oxidative, photolytic, thermal, evaporative) during processing or upon storage of the oral product. In such embodiments, the active ingredient (such as caffeine, vitamin A, and iron (Fe)) may be encapsulated, or the matrix otherwise modified with fillers, binders, and the like, to provide

enhanced stability to the active ingredient. For example, binders such as functional celluloses (e.g., cellulose ethers including, but not limited to, hydroxypropyl cellulose) may be employed to enhance stability of such actives toward degradation. Additionally, encapsulated actives may need to be paired with an excipient in the composition to increase their solubility and/or bioavailability. Non-limiting examples of suitable excipients include beta-carotene, lycopene, Vitamin D, Vitamin E, Co-enzyme Q10, Vitamin K, and curcumin.

In other embodiments, in order to provide a desired concentration of the active ingredient by weight, an initial quantity of the active ingredient may be increased to compensate for a gradual degradative loss. Accordingly, larger initial amounts than those disclosed herein are contemplated by the present disclosure.

Antioxidants

In some embodiments, the active ingredient comprises one or more antioxidants. As used herein, the term "antioxidant" refers to a substance which prevents or suppresses oxidation by terminating free radical reactions, and may delay or prevent some types of cellular damage. Antioxidants may be naturally occurring or synthetic. Naturally occurring antioxidants include those found in foods and botanical materials. Non-limiting examples of antioxidants include certain botanical materials, vitamins, polyphenols, and phenol derivatives.

Examples of botanical materials which are associated with antioxidant characteristics include without limitation acai berry, alfalfa, allspice, annatto seed, apricot oil, basil, bee balm, wild bergamot, black pepper, blueberries, borage seed oil, bugleweed, cacao, calamus root, catnip, catuaba, cayenne pepper, chaga mushroom, chervil, cinnamon, dark chocolate, potato peel, grape seed, ginseng, gingko biloba, Saint John's Wort, saw palmetto, green tea, black tea, black cohosh, cayenne, chamomile, cloves, cocoa powder, cranberry, dandelion, grapefruit, honeybush, echinacea, garlic, evening primrose, feverfew, ginger, goldenseal, hawthorn, hibiscus flower, jiaogulan, kava, lavender, licorice, marjoram, milk thistle, mints (menthe), oolong tea, beet root, orange, oregano, papaya, pennyroyal, peppermint, red clover, rooibos (red or green), rosehip, rosemary, sage, clary sage, savory, spearmint, spirulina, slippery elm bark, sorghum bran hi-tannin, sorghum grain hi-tannin, sumac bran, comfrey leaf and root, goji berries, gutu kola, thyme, turmeric, uva ursi, valerian, wild yam root, wintergreen, yacon root, yellow dock, yerba mate, yerba santa, bacopa monniera, withania somnifera, Lion’s mane, and silybum marianum. Such botanical materials may be provided in fresh or dry form, essential oils, or may be in the form of an extracts. The botanical materials (as well as their extracts) often include compounds from various classes known to provide antioxidant effects, such as minerals, vitamins, isoflavones, phytoesterols, allyl sulfides, dithiolthiones, isothiocyanates, indoles, lignans, flavonoids, polyphenols, and carotenoids. Examples of compounds found in botanical extracts or oils include ascorbic acid, peanut endocarb, resveratrol, sulforaphane, beta-

carotene, lycopene, lutein, co-enzyme Q, carnitine, quercetin, kaempferol, and the like. See, e.g., Santhosh et al., Phytomedicine, 12(2005) 216-220, which is incorporated herein by reference.

Non-limiting examples of other suitable antioxidants include citric acid, Vitamin E or a derivative thereof, a tocopherol, epicatechol, epigallocatechol, epigallocatechol gallate, erythorbic acid, sodium erythorbate, 4-hexylresorcinol, theaflavin, theaflavin monogallate A or B, theaflavin digallate, phenolic acids, glycosides, quercitrin, isoquercitrin, hyperoside, polyphenols, catechols, resveratrols, oleuropein, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), tertiary butylhydroquinone (TBHQ), and combinations thereof. In some embodiments, the antioxidant is Vitamin E or a derivative thereof, a flavonoid, a polyphenol, a carotenoid, or a combination thereof.

When present, an antioxidant is typically at a concentration of from about 0.001% w/w to about 10% by weight, such as, e.g., from about 0.001%, about 0.005%, about 0.01% w/w, about 0.05%, about 0.1%, or about 0.5%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, or about 10%, based on the total weight of the composition.

Nicotine component

In certain embodiments, the active ingredient comprises a nicotine component. In some embodiments, the active ingredient is a nicotine component (i.e., nicotine is the sole active ingredient). By "nicotine component" is meant any suitable form of nicotine (e.g., free base or salt) for providing oral absorption of at least a portion of the nicotine present.

The source of the nicotine may vary, and may be natural or synthetic. Most preferably, the nicotine is naturally occurring and obtained as an extract from a *Nicotiana* species (e.g., tobacco). The nicotine can have the enantiomeric form S(-)-nicotine, R(+)-nicotine, or a mixture of S(-)-nicotine and R(+)-nicotine. Most preferably, the nicotine is in the form of S(-)-nicotine (e.g., in a form that is virtually all S(-)-nicotine) or a racemic mixture composed primarily or predominantly of S(-)-nicotine (e.g., a mixture composed of about 95 weight parts S(-)-nicotine and about 5 weight parts R(+)-nicotine). Most preferably, the nicotine is employed in virtually pure form or in an essentially pure form. Highly preferred nicotine that is employed has a purity of greater than about 95 percent, more preferably greater than about 98 percent, and most preferably greater than about 99 percent, on a weight basis.

Typically, the nicotine component is selected from the group consisting of nicotine free base and a nicotine salt. In some embodiments, the nicotine component is nicotine in its free base form, which easily can be adsorbed in for example, a microcrystalline cellulose material to form a microcrystalline cellulose-nicotine carrier complex. See, for example, the discussion of nicotine in free base form in US Pat. Pub. No. 2004/0191322 to Hansson, which is incorporated herein by reference.

In some embodiments, at least a portion of the nicotine component can be employed in the form of a salt. Salts of nicotine can be provided using the types of ingredients and techniques set forth in US Pat. No. 2,033,909 to Cox et al. and Perfetti, *Beitrage Tabakforschung Int.*, 12: 43-54 (1983), which are incorporated herein by reference. Additionally, salts of nicotine are available from sources such as Pfaltz and Bauer, Inc. and K&K Laboratories, Division of ICN Biochemicals, Inc. Typically, the nicotine component is selected from the group consisting of nicotine free base, a nicotine salt such as hydrochloride, dihydrochloride, monotartrate, bitartrate, sulfate, salicylate, and nicotine zinc chloride. In some embodiments, the nicotine component is nicotine bitartrate. In some embodiments, the nicotine component comprises or is nicotine benzoate.

In some embodiments, at least a portion of the nicotine can be in the form of a resin complex of nicotine, where nicotine is bound in an ion-exchange resin, such as nicotine polacrilex, which is nicotine bound to, for example, a polymethacrilic acid, such as Amberlite IRP64, Purolite C115HMR, or Doshion P551. See, for example, US Pat. No. 3,901,248 to Lichtneckert et al., which is incorporated herein by reference. Another example is a nicotine-polyacrylic carbomer complex, such as with Carbopol 974P. In some embodiments, nicotine may be present in the form of a nicotine polyacrylic complex. In some embodiments, the composition comprises nicotine polacrilex.

In some embodiments, the only nicotine present in the composition is that added in the form of resin-bound nicotine (e.g., nicotine polacrilex). In some embodiments, the composition comprises resin-bound nicotine (e.g., nicotine polacrilex), and further comprises free base nicotine, a nicotine salt, ion paired nicotine, or combinations thereof. In some embodiments, at least a portion of the nicotine present in the composition is present as an ion pair as described further herein below.

Typically, the nicotine component (calculated as the free base) when present, is in a concentration of at least about 0.001% by weight of the composition, such as in a range from about 0.001% to about 10%. In some embodiments, the nicotine component is present in a concentration from about 0.1% w/w to about 10% by weight, such as, e.g., from about 0.1% w/w, about 0.2%, about 0.3%, about 0.4%, about 0.5% about 0.6%, about 0.7%, about 0.8%, or about 0.9%, to about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, or about 10% by weight, calculated as the free base and based on the total weight of the composition. In some embodiments, the nicotine component is present in a concentration from about 0.1% w/w to about 3% by weight, such as, e.g., from about 0.1% w/w to about 2.5%, from about 0.1% to about 2.0%, from about 0.1% to about 1.5%, or from about 0.1% to about 1% by weight, calculated as the free base and based on the total weight of the composition.

The total amount of nicotine present may be provided by more than one source of nicotine, such as various combinations of any of nicotine free base, nicotine salt, ion paired nicotine, and resin-bound nicotine (e.g., nicotine polacrilex).

In other embodiments, the products or compositions of the disclosure can be characterized as completely free or substantially free of any nicotine component (e.g., any embodiment as disclosed herein may be completely or substantially free of any nicotine component). By "substantially free" is meant that no nicotine has been intentionally added, beyond trace amounts that may be naturally present in e.g., a botanical material. For example, certain embodiments can be characterized as having less than 0.001% by weight of nicotine, or less than 0.0001%, or even 0% by weight of nicotine, calculated as the free base.

Cannabinoids

In some embodiments, the active ingredient comprises one or more cannabinoids. As used herein, the term "cannabinoid" refers to a class of diverse natural or synthetic chemical compounds that acts on cannabinoid receptors (i.e., CB1 and CB2) in cells that alter neurotransmitter release in the brain. Cannabinoids are cyclic molecules exhibiting particular properties such as the ability to easily cross the blood-brain barrier. Cannabinoids may be naturally occurring (Phytocannabinoids) from plants such as cannabis, (endocannabinoids) from animals, or artificially manufactured (synthetic cannabinoids). Cannabis species express at least 85 different phytocannabinoids, and these may be divided into subclasses, including cannabigerols, cannabichromenes, cannabidiols, tetrahydrocannabinols, cannabinols and cannabinodiols, and other cannabinoids, such as cannabigerol (CBG), cannabichromene (CBC), cannabidiol (CBD), tetrahydrocannabinol (THC), cannabinol (CBN) and cannabinodiol (CBDL), cannabicyclol (CBL), cannabivarin (CBV), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), cannabichromevarin (CBCV), cannabigerovarin (CBGV), cannabigerol monomethyl ether (CBGM), cannabinerolic acid, cannabidiolic acid (CBDA), Cannabinol propyl variant (CBNV), cannabitriol (CBO), tetrahydrocannabmolic acid (THCA), and tetrahydrocannabivarinic acid (THCV A).

In some embodiments, the cannabinoid is selected from the group consisting of cannabigerol (CBG), cannabichromene (CBC), cannabidiol (CBD), tetrahydrocannabinol (THC), cannabinol (CBN) and cannabinodiol (CBDL), cannabicyclol (CBL), cannabivarin (CBV), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), cannabichromevarin (CBCV), cannabigerovarin (CBGV), cannabigerol monomethyl ether (CBGM), cannabinerolic acid, cannabidiolic acid (CBDA), Cannabinol propyl variant (CBNV), cannabitriol (CBO), tetrahydrocannabmolic acid (THCA), tetrahydrocannabivarinic acid (THCV A), and mixtures thereof. In some embodiments, the cannabinoid comprises at least tetrahydrocannabinol (THC). In some embodiments, the cannabinoid is tetrahydrocannabinol (THC). In some embodiments, the cannabinoid comprises at least cannabidiol (CBD). In some embodiments, the cannabinoid is cannabidiol (CBD). In some embodiments, the CBD is synthetic CBD. Notably, CBD has a logP value of about 6.5, making it insoluble in an aqueous environment (e.g., saliva).

In some embodiments, the cannabinoid (e.g., CBD) is added to the oral product in the form of an isolate. An isolate is an extract from a plant, such as cannabis, where the active material of interest (in this case the cannabinoid, such as CBD) is present in a high degree of purity, for example greater than 95%, greater than 96%, greater than 97%, greater than 98%, or around 99% purity.

In some embodiments, the cannabinoid is an isolate of CBD in a high degree of purity, and the amount of any other cannabinoid in the oral product is no greater than about 1% by weight of the oral product, such as no greater than about 0.5% by weight of the oral product, such as no greater than about 0.1% by weight of the oral product, such as no greater than about 0.01% by weight of the oral product.

The choice of cannabinoid and the particular percentages thereof which may be present within the disclosed oral product will vary depending upon the desired flavor, texture, and other characteristics of the oral product.

In some embodiments, the cannabinoid (such as CBD) is present in the composition in a concentration of at least about 0.001% by weight of the oral product, such as in a range from about 0.001% to about 2% by weight of the oral product. In some embodiments, the cannabinoid (such as CBD) is present in the composition in a concentration of from about 0.1% to about 1.5% by weight, based on the total weight of the composition. In some embodiments, the cannabinoid (such as CBD) is present in a concentration from about 0.4% to about 1.5% by weight, based on the total weight of the oral composition.

Alternatively, or in addition to the cannabinoid, the active ingredient may include a cannabimimetic, which is a class of compounds derived from plants other than cannabis that have biological effects on the endocannabinoid system similar to cannabinoids. Examples include yangonin, alpha-amyrin or beta-amyrin (also classified as terpenes), cyanidin, curcumin (tumeric), catechin, quercetin, salvinorin A, N-acylethanolamines, and N-alkylamide lipids. Such compounds can be used in the same amounts and ratios noted herein for cannabinoids.

Terpenes

Active ingredients suitable for use in the present disclosure can also be classified as terpenes, many of which are associated with biological effects, such as calming effects. Terpenes are understood to have the general formula of $(C_5H_8)_n$ and include monoterpenes, sesquiterpenes, and diterpenes. Terpenes can be acyclic, monocyclic or bicyclic in structure. Some terpenes provide an entourage effect when used in combination with cannabinoids or cannabimimetics. Examples include beta-caryophyllene, linalool, limonene, beta-citronellol, linalyl acetate, pinene (alpha or beta), geraniol, carvone, eucalyptol, menthone, iso-menthone, piperitone, myrcene, beta-bourbonene, and germacrene, which may be used singly or in combination.

In some embodiments, the terpene is a terpene derivable from a phytocannabinoid producing plant, such as a plant from the stain of the cannabis sativa species, such as hemp. Suitable terpenes in this regard include so-called “C10” terpenes, which are those terpenes comprising 10 carbon atoms, and so-called “C15” terpenes, which are those terpenes comprising 15 carbon atoms. In some embodiments, the active ingredient comprises more than one terpene. For example, the active ingredient may comprise one, two, three, four, five, six, seven, eight, nine, ten or more terpenes as defined herein. In some embodiments, the terpene is selected from pinene (alpha and beta), geraniol, linalool, limonene, carvone, eucalyptol, menthone, iso-menthone, piperitone, myrcene, beta-bourbonene, germacrene and mixtures thereof.

Pharmaceutical ingredients

The pharmaceutical ingredient can be any known agent adapted for therapeutic, prophylactic, or diagnostic use. These can include, for example, synthetic organic compounds, proteins and peptides, polysaccharides and other sugars, lipids, inorganic compounds, and nucleic acid sequences, having therapeutic, prophylactic, or diagnostic activity. Non-limiting examples of pharmaceutical ingredients include analgesics and antipyretics (e.g., acetylsalicylic acid, acetaminophen, 3-(4-isobutylphenyl)propanoic acid).

Bleached active ingredient

In some embodiments, the composition comprises an active ingredient as disclosed herein, wherein the active ingredient is characterized as bleached. Such a bleached active ingredient may be desirable e.g., to prevent tooth discoloration during use of the oral product, or so that any residue remaining in the mouth of the user after use of the product is less visible, and is less likely to cause staining of fibrous materials, such as clothing, that may contact the residue. By "bleached" active ingredient is meant an active ingredient (e.g., a botanical material or derivative thereof), which, in its natural state possesses a color, and which has been treated to reduce or eliminate the color. By "color" is meant the characteristic of human visual perception described through color categories, with names such as red, blue, yellow (primary colors) or brown, orange, green, purple, and the like, resulting from combinations of primary colors. This perception of color derives from the stimulation of cone cells in the human eye by electromagnetic radiation in the visible spectrum, associated with objects through the wavelength of the light that is reflected from them. This reflection is governed by the object's physical properties such as e.g., absorption and emission spectra across the electromagnetic spectrum.

Certain active ingredients, by virtue of naturally occurring chemical compounds therein which reflect light in the visible range of the electromagnetic spectrum, impart a color to the active ingredient (e.g., chlorophyll or pigment decomposition products in certain botanical materials, responsible for green color and brown colors, respectively). Such chemical compounds, or a portion

thereof, which are responsible for the color of the active ingredient, may be chemically altered or removed by various treatments. In some embodiments, the treatment is effective to eliminate at least 70% of the chemicals present in the active ingredient having maximum transmission of wavelengths in the visible range of the electromagnetic spectrum, based on the weight of the naturally occurring compounds. For example, such treatment may be effective to remove 70%, 80%, 90%, 95%, 99%, or even 100% of the naturally occurring compounds responsible for the visible color of the active ingredient.

In some embodiments, the treatment for bleaching (i.e., altering or removing colored chemical compounds from the active ingredient) includes extraction, chemical bleaching, or a combination thereof. One particularly suitable extraction method is supercritical carbon dioxide (CO_2) extraction. Methods of chemical bleaching of e.g., botanical materials, including tobacco, are known, and include as non-limiting examples, treatment with hydrogen peroxide, ozone, or other oxidizing agents. For example, bleached active ingredients (e.g., a bleached botanical or tobacco material) may be produced by various whitening methods using various bleaching or oxidizing agents. Example oxidizing agents include peroxides (e.g., hydrogen peroxide), chlorite salts, chlorate salts, perchlorate salts, hypochlorite salts, ozone, ammonia, potassium permanganate, and combinations thereof. Oxidation catalysts can be used. Example oxidation catalysts are titanium dioxide, manganese dioxide, and combinations thereof.

Methods of bleaching known for bleaching tobacco may be applied to the present active ingredients. Processes for treating tobacco with bleaching agents are discussed, for example, in U.S. Pat. Nos. 787,611 to Daniels, Jr.; 1,086,306 to Oelenheinz; 1,437,095 to Delling; 1,757,477 to Rosenhoch; 2,122,421 to Hawkinson; 2,148,147 to Baier; 2,170,107 to Baier; 2,274,649 to Baier; 2,770,239 to Prats et al.; 3,612,065 to Rosen; 3,851,653 to Rosen; 3,889,689 to Rosen; 3,943,940 to Minami; 3,943,945 to Rosen; 4,143,666 to Rainer; 4,194,514 to Campbell; 4,366,823, 4,366,824, and 4,388,933 to Rainer et al.; 4,641,667 to Schmekel et al.; 5,713,376 to Berger; 9,339,058 to Byrd Jr. et al.; 9,420,825 to Beeson et al.; and 9,950,858 to Byrd Jr. et al.; as well as in US Pat. App. Pub. Nos. 2012/0067361 to Bjorkholm et al.; 2016/0073686 to Crooks; 2017/0020183 to Bjorkholm; and 2017/0112183 to Bjorkholm, and in PCT Publ. Appl. Nos. WO1996/031255 to Giolvas and WO2018/083114 to Bjorkholm, all of which are incorporated herein by reference.

In some embodiments, the bleached active agent, or the composition or product comprising the bleached active agent, can have an ISO brightness of at least about 50%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, or at least about 80%. In some embodiments, the bleached active agent or the composition or product comprising the bleached active agent, can have an ISO brightness in the range of about 50% to about 90%, about 55% to about 75%, or about 60% to about 70%. ISO brightness can be measured according to ISO 3688:1999 or ISO 2470-1:2016.

In some embodiments, the bleached active agent can be characterized as lightened in color (e.g., "whitened") in comparison to an untreated active agent. White colors are often defined with reference to the International Commission on Illumination's (CIE's) chromaticity diagram. The bleached active agent or the composition or product comprising the bleached active agent, can, in certain embodiments, be characterized as closer on the chromaticity diagram to pure white than an untreated active agent or composition or product comprising an untreated active agent.

Whiteness values of bleached active ingredients, compositions, and pouched products comprising such ingredients, may be determined according to the Commission Internationale de l'Eclairage (CIE) model, for example, with a hand-held color meter, relative to a control product (See "Precise Color Communication; Color Control from Perception to Instrumentation," Konica Minolta, 2007; http://konicaminolta.com/instruments/about/network, which is incorporated herein by reference). Discoloration from white may be evaluated by the E313 Whiteness Index according to ASTM method E313, using the formula WI = (3.388Z-3Y, where Y and Z are the CIE tri-stimulus values, and measured by a hand-held meter.

Flavoring agents

In some embodiments, the composition comprises a flavoring agent. As used herein, a "flavoring agent" or "flavorant" is any flavorful or aromatic substance capable of altering the sensory characteristics associated with the oral product. Examples of sensory characteristics that can be modified by the flavoring agent include taste, mouthfeel, moistness, coolness/heat, and/or fragrance/aroma. Flavoring agents may be natural or synthetic, and the character of the flavors imparted thereby may be described, without limitation, as fresh, sweet, herbal, confectionary, floral, fruity, or spicy. Specific types of flavors include, but are not limited to, vanilla, coffee, chocolate/cocoa, cream, mint, spearmint, menthol, peppermint, wintergreen, eucalyptus, lavender, cardamon, nutmeg, cinnamon, clove, cascarilla, sandalwood, honey, jasmine, ginger, anise, sage, licorice, lemon, orange, apple, peach, lime, cherry, strawberry, trigeminal sensates, terpenes and any combinations thereof. See also, Leffingwell et al., Tobacco Flavoring for Smoking Products, R. J. Reynolds Tobacco Company (1972), which is incorporated herein by reference. Flavoring agents also may include components that are considered moistening, cooling or smoothening agents, such as eucalyptus. These flavors may be provided neat (i.e., alone) or in a composite, and may be employed as concentrates or flavor packages (e.g., spearmint and menthol, orange and cinnamon; lime, pineapple, and the like). Representative types of components also are set forth in US Pat. No. 5,387,416 to White et al.; US Pat. App. Pub. No. 2005/0244521 to Strickland et al.; and PCT Application Pub. No. WO 05/041699 to Quinter et al., each of which is incorporated herein by reference.

In some instances, the flavoring agent may be provided in a spray-dried form or a liquid form. In some embodiments, a liquid flavorant is disposed (i.e., adsorbed or absorbed in or on) a porous particulate carrier, for example microcrystalline cellulose, which is then combined with the other composition ingredients. Embodiments with flavorant present in dry form (e.g., in or on microcrystalline cellulose) may be advantageous in providing a more homogenous product.

The amount of flavoring agent utilized in the composition can vary, but is typically up to about 10% by weight, and certain embodiments are characterized by a flavoring agent content of at least about 0.1% by weight, such as about 0.5 to about 10%, about 1 to about 5%, or about 2 to about 4% weight, based on the total weight of the composition.

Taste modifiers

In order to improve the organoleptic properties of a composition as disclosed herein, the composition may include one or more taste modifying agents ("taste modifiers") which may serve to mask, alter, block, or improve e.g., the flavor of a composition as described herein. Non-limiting examples of such taste modifiers include analgesic or anesthetic herbs, spices, and flavors which produce a perceived cooling (e.g., menthol, eucalyptus, mint), warming (e.g., cinnamon), or painful (e.g., capsaicin) sensation. Certain taste modifiers fall into more than one overlapping category.

In some embodiments, the taste modifier modifies one or more of bitter, sweet, salty, or sour tastes. In some embodiments, the taste modifier targets pain receptors. In some embodiments, the composition comprises an active ingredient having a bitter taste, and a taste modifier which masks or blocks the perception of the bitter taste. In some embodiments, the taste modifier is a substance which targets pain receptors (e.g., vanilloid receptors) in the user's mouth to mask e.g., a bitter taste of another component (e.g., an active ingredient). In some embodiments, the taste modifier is capsaicin.

In some embodiments, the taste modifier is the amino acid gamma-amino butyric acid (GABA), referenced herein above with respect to amino acids. Studies in mice suggest that GABA may serve function(s) in taste buds in addition to synaptic inhibition. See, e.g., Dvoryanchikov et al., J Neurosci. 2011 Apr 13;31(15):5782-91. Without wishing to be bound by theory, GABA may suppress the perception of certain tastes, such as bitterness. In some embodiments, the composition comprises caffeine and GABA.

In some embodiments, the taste modifier is adenosine monophosphate (AMP). AMP is a naturally occurring nucleotide substance which can block bitter food flavors or enhance sweetness. It does not directly alter the bitter flavor, but may alter human perception of "bitter" by blocking the associated receptor.

In some embodiments, the taste modifier is lactisole. Lactisole is an antagonist of sweet taste receptors. Temporarily blocking sweetness receptors may accentuate e.g., savory notes.

When present, a representative amount of taste modifier is about 0.01% by weight or more, about 0.1% by weight or more, or about 1.0% by weight or more, but will typically make up less than about 10% by weight of the total weight of the composition, (e.g., from about 0.01%, about 0.05%, about 0.1%, or about 0.5%, to about 1%, about 5%, or about 10% by weight of the total weight of the composition).

Salts

In some embodiments, the composition comprises a salt (e.g., an alkali metal salt), typically employed in an amount sufficient to provide desired sensory attributes to the composition. Non-limiting examples of suitable salts include sodium chloride, potassium chloride, ammonium chloride, flour salt, sodium acetate, sodium citrate, and the like. In some embodiments, the salt is sodium chloride, ammonium chloride, or a combination thereof.

When present, a representative amount of salt is about 0.5% by weight or more, about 1.0% by weight or more, or about 1.5% by weight or more, but will typically make up about 10% or less of the total weight of the composition, or about 7.5% or less, or about 5% or less (e.g., from about 0.5 to about 5% by weight).

Sweeteners

In order to improve the sensory properties of the composition according to the disclosure, one or more sweeteners may be added. The sweeteners can be any sweetener or combination of sweeteners, in natural or artificial form, or as a combination of natural and artificial sweeteners. Examples of natural sweeteners include fructose, sucrose, glucose, maltose, isomaltulose, mannose, galactose, lactose, stevia, honey, and the like. Examples of artificial sweeteners include sucralose, maltodextrin, saccharin, aspartame, acesulfame K, neotame, and the like. In some embodiments, the sweetener comprises one or more sugar alcohols. Sugar alcohols are polyols derived from monosaccharides or disaccharides that have a partially or fully hydrogenated form. Sugar alcohols have, for example, about 4 to about 20 carbon atoms and include erythritol, arabitol, ribitol, isomalt, maltitol, dulcitol, iditol, mannitol, xylitol, lactitol, sorbitol, and combinations thereof (e.g., hydrogenated starch hydrolysates). In some embodiments, the sweetener is xylitol, sucralose, or a combination thereof.

When present, a sweetener or combination of sweeteners may make up from about 0.1 to about 20% or more of the of the composition by weight, for example, from about 0.1 to about 1%, from about 1 to about 5%, from about 5 to about 10%, or from about 10 to about 20% by weight, based on the total weight of the composition. In some embodiments, a combination of sweeteners is present at a concentration of from about 1% to about 3% by weight of the composition.

Water

The water content of the composition, prior to use by a consumer of the pouched product, may vary according to the desired properties. Typically, the composition is less than about 15% by weight of water, and generally is from about 0.01 to about 10% by weight of water, for example, from about 0.01 to about 1, about 1 to about 10, or about 1 to about 5% by weight, based on the total weight of the composition.

Ion Pairing

In some embodiments, the composition as disclosed herein comprises a basic amine. By "basic amine" is meant a molecule including at least one basic amine functional group. Examples of basic amines include, but are not limited to, alkaloids. By "basic amine functional group" is meant a group containing a nitrogen atom having a lone pair of electrons. The basic amine functional group is attached to or incorporated within the molecule through one or more covalent bonds to the said nitrogen atom. The basic amine may be a primary, secondary, or tertiary amine, meaning the nitrogen bears one, two, or three covalent bonds to carbon atoms. By virtue of the lone pair of electrons on the nitrogen atom, such amines are termed "basic", meaning the lone electron pair is available for hydrogen bonding. The basicity (i.e., the electron density on the nitrogen atom and consequently the availability and strength of hydrogen bonding to the nitrogen atom) of the basic amine may be influenced by the nature of neighboring atoms, the steric bulk of the molecule, and the like.

Generally, the basic amine is present in or as an active ingredient in the composition, as described herein above. In some embodiments, the basic amine is caffeine. In some embodiments, the basic amine is nicotine or a nicotine component, each as described herein above. Generally, the basic amine (e.g., nicotine) is released from the composition and absorbed through the oral mucosa, thereby entering the blood stream, where it is circulated systemically.

In some embodiments, the composition as described herein comprises an organic acid, an alkali metal salt thereof, or a combination thereof, each as described further herein below. In some embodiments, at least a portion of the basic amine is associated with at least a portion of the organic acid or the alkali metal salt thereof. Depending on multiple variables (concentration, pH, nature of the organic acid, and the like), the basic amine present in the composition can exist in multiple forms, including ion paired, in solution (i.e., fully solvated), as the free base, as a cation, as a salt, or any combination thereof. In some embodiments, the association between the basic amine and at least a portion of the organic acid or an alkali metal salt thereof, is in the form of an ion pair between the basic amine and a conjugate base of the organic acid.

Ion pairing describes the partial association of oppositely charged ions in relatively concentrated solutions to form distinct chemical species called ion pairs. The strength of the association (i.e., the ion pairing) depends on the electrostatic force of attraction between the positive

and negative ions (i.e., protonated basic amine and the conjugate base of the organic acid). By "conjugate base" is meant the base resulting from deprotonation of the corresponding acid (e.g., benzoate is the conjugate base of benzoic acid). On average, a certain population of these ion pairs exists at any given time, although the formation and dissociation of ion pairs is continuous. In the composition as disclosed herein, and/or upon oral use of said composition (e.g., upon contact with saliva), the basic amine and the conjugate base of the organic acid exist at least partially in the form of an ion pair. Without wishing to be bound by theory, it is believed that such ion pairing may minimize chemical degradation of the basic amine and/or enhance the oral availability of the basic amine (e.g., nicotine).

One of skill in the art will recognize that the extent of ion pairing in the disclosed compositions, both before and during use by the consumer, may vary based on, for example, pH, the nature of the organic acid, the concentration of basic amine (e.g., nicotine), the concentration of the organic acid or conjugate base of the organic acid present in the composition, the moisture content of the composition, and the like. One of skill in the art will also recognize that ion pairing is an equilibrium process influenced by the foregoing variables. Accordingly, quantification of the extent of ion pairing is difficult or impossible by calculation or direct observation. However, the presence of ion pairing may be demonstrated through surrogate measures such as partitioning between octanol and water or membrane permeation of aqueous solutions of e.g., nicotine plus organic acids and/or their conjugate bases. Particularly, an octanol-water partitioning favoring distribution of a basic amine-organic acid ion pair into octanol is predictive of good absorption of the basic amine present in the composition through the oral mucosa.

Organic acid

As described herein above, in some embodiments, the composition comprises an organic acid. As used herein, the term "organic acid" refers to an organic (i.e., carbon-based) compound that is characterized by acidic properties. Typically, organic acids are relatively weak acids (i.e., they do not dissociate completely in the presence of water), such as carboxylic acids (-CO_2H) or sulfonic acids (-SO_2OH). As used herein, reference to organic acid means an organic acid that is intentionally added. In this regard, an organic acid may be intentionally added as a specific composition ingredient as opposed to merely being inherently present as a component of another composition ingredient (e.g., the small amount of organic acid which may inherently be present in a composition ingredient, such as a tobacco material).

Suitable organic acids will typically have a range of lipophilicities (i.e., a polarity giving an appropriate balance of water and organic solubility). Lipophilicity is conveniently measured in terms of logP, the partition coefficient of a molecule between a lipophilic phase and an aqueous phase,

usually octanol and water, respectively. Typically, lipophilicities of suitable organic acids, as indicated by logP, will vary between about 1.4 and about 4.5 (more soluble in octanol than in water). In some embodiments, the organic acid has a logP value of from about 1.5 to about 4.0, e.g., from about 1.5, about 2.0, about 2.5, or about 3.0, to about 3.5, about 4.0, about 4.5, or about 5.0. Particularly suitable organic acids have a logP value of from about 1.7 to about 4, such as from about 2.0, about 2.5, or about 3.0, to about 3.5, or about 4.0. In specific embodiments, the organic acid has a logP value of about 2.5 to about 3.5. In some embodiments, organic acids outside this range may also be utilized for various purposes and in various amounts, as described further herein below. For example, in some embodiments, the organic acid may have a logP value of greater than about 4.5, such as from about 4.5 to about 8.0. Particularly, the presence of certain solvents or solubilizing agents (e.g., inclusion in the composition of glycerin or propylene glycol) may extend the range of lipophilicity (i.e., values of logP higher than 4.5, such as from about 4.5 to about 8.0).

Without wishing to be bound by theory, it is believed that moderately lipophilic organic acids (e.g., logP of from about 1.4 to about 4.5) produce ion pairs with basic amine-containing active ingredients (e.g., nicotine) which are of a polarity providing good octanol-water partitioning of the ion pair, and hence partitioning of the active ingredient (e.g., nicotine), into octanol versus water. Such partitioning into octanol is predictive of favorable oral availability of the active ingredient. In some embodiments, the organic acid has a logP value of from about 1.4 to about 4.5, such as about 1.5, about 2, about 2.5, about 3, about 3.5, about 4 or about 4.5. In some embodiments, the organic acid has a logP value of from about 2.5 to about 3.5.

In some embodiments, the organic acid is a carboxylic acid or a sulfonic acid. The carboxylic acid or sulfonic acid functional group may be attached to any alkyl, cycloalkyl, heterocycloalkyl, aryl, or heteroaryl group having, for example, from one to twenty carbon atoms (C_1-C_{20}). In some embodiments, the organic acid is an alkyl, cycloalkyl, heterocycloalkyl, aryl, or heteroaryl carboxylic or sulfonic acid.

As used herein, "alkyl" refers to any straight chain or branched chain hydrocarbon. The alkyl group may be saturated (i.e., having all sp^3 carbon atoms), or may be unsaturated (i.e., having at least one site of unsaturation). As used herein, the term "unsaturated" refers to the presence of a carbon-carbon, sp^2 double bond in one or more positions within the alkyl group. Unsaturated alkyl groups may be mono- or polyunsaturated. Representative straight chain alkyl groups include, but are not limited to, methyl, ethyl, n-propyl, n-butyl, n-pentyl, and n-hexyl. Branched chain alkyl groups include, but are not limited to, isopropyl, sec-butyl, isobutyl, tert-butyl, isopentyl, and 2-methylbutyl. Representative unsaturated alkyl groups include, but are not limited to, ethylene or vinyl, allyl, 1-butenyl, 2-butenyl, isobutylenyl, 1-pentenyl, 2-pentenyl, 3-methyl-1-butenyl, 2-methyl-2-butenyl, 2,3-dimethyl-2-butenyl, and the like. An alkyl group can be unsubstituted or substituted.

"Cycloalkyl" as used herein refers to a carbocyclic group, which may be mono- or bicyclic. Cycloalkyl groups include rings having 3 to 7 carbon atoms as a monocycle or 7 to 12 carbon atoms as a bicycle. Examples of monocyclic cycloalkyl groups include cyclopropyl, cyclobutyl, cyclopentyl, cyclohexyl, cycloheptyl, and cyclooctyl. A cycloalkyl group can be unsubstituted or substituted, and may include one or more sites of unsaturation (e.g., cyclopentenyl or cyclohexenyl).

The term "aryl" as used herein refers to a carbocyclic aromatic group. Examples of aryl groups include, but are not limited to, phenyl and naphthyl. An aryl group can be unsubstituted or substituted.

"Heteroaryl" and "heterocycloalkyl" as used herein refer to an aromatic or non-aromatic ring system, respectively, in which one or more ring atoms is a heteroatom, e.g. nitrogen, oxygen, and sulfur. The heteroaryl or heterocycloalkyl group comprises up to 20 carbon atoms and from 1 to 3 heteroatoms selected from N, O, and S. A heteroaryl or heterocycloalkyl may be a monocycle having 3 to 7 ring members (for example, 2 to 6 carbon atoms and 1 to 3 heteroatoms selected from N, O, and S) or a bicycle having 7 to 10 ring members (for example, 4 to 9 carbon atoms and 1 to 3 heteroatoms selected from N, O, and S), for example: a bicyclo[4,5], [5,5], [5,6], or [6,6] system. Examples of heteroaryl groups include by way of example and not limitation, pyridyl, thiazolyl, tetrahydrothiophenyl, pyrimidinyl, furanyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, tetrazolyl, benzofuranyl, thianaphthalenyl, indolyl, indolenyl, quinolinyl, isoquinolinyl, benzimidazolyl, isoxazolyl, pyrazinyl, pyridazinyl, indolizinyl, isoindolyl, 3H-indolyl, 1H-indazolyl, purinyl, 4H-quinolizinyl, phthalazinyl, naphthyridinyl, quinoxalinyl, quinazolinyl, cinnolinyl, pteridinyl, 4aH-carbazolyl, carbazolyl, phenanthridinyl, acridinyl, pyrimidinyl, phenanthrolinyl, phenazinyl, phenothiazinyl, furazanyl, phenoxazinyl, isochromanyl, chromanyl, imidazolidinyl, imidazolinyl, pyrazolidinyl, pyrazolinyl, benzotriazolyl, benzisoxazolyl, and isatinoyl. Examples of heterocycloalkyls include by way of example and not limitation, dihydroypyridyl, tetrahydropyridyl (piperidyl), tetrahydrothiophenyl, piperidinyl, 4-piperidonyl, pyrrolidinyl, 2-pyrrolidonyl, tetrahydrofuranyl, tetrahydropyranyl, bis-tetrahydropyranyl, tetrahydroquinolinyl, tetrahydroisoquinolinyl, decahydroquinolinyl, octahydroisoquinolinyl, piperazinyl, quinuclidinyl, and morpholinyl. Heteroaryl and heterocycloalkyl groups can be unsubstituted or substituted.

"Substituted" as used herein and as applied to any of the above alkyl, aryl, cycloalkyl, heteroaryl, heterocyclyl, means that one or more hydrogen atoms are each independently replaced with a substituent. Typical substituents include, but are not limited to, -Cl, Br, F, alkyl, -OH, $-OCH_3$, NH_2, $-NHCH_3$, $-N(CH_3)_2$, -CN, $-NC(=O)CH_3$, -C(=O)-, $-C(=O)NH_2$, and $-C(=O)N(CH_3)_2$. Wherever a group is described as "optionally substituted," that group can be substituted with one or more of the above substituents, independently selected for each occasion. In some embodiments, the substituent may be one or more methyl groups or one or more hydroxyl groups.

In some embodiments, the organic acid is an alkyl carboxylic acid. Non-limiting examples of alkyl carboxylic acids include formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, heptanoic acid, octanoic acid, nonanoic acid, decanoic acid, undecanoic acid, dodecanoic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, and the like.

In some embodiments, the organic acid is an alkyl sulfonic acid. Non-limiting examples of alkyl sulfonic acids include propanesulfonic acid, heptanesulfonic acid, and octanesulfonic acid.

In some embodiments, the alkyl carboxylic or sulfonic acid is substituted with one or more hydroxyl groups. Non-limiting examples include glycolic acid, 4-hydroxybutyric acid, and lactic acid.

In some embodiments, an organic acid may include more than one carboxylic acid group or more than one sulfonic acid group (*e.g.*, two, three, or more carboxylic acid groups). Non-limiting examples include oxalic acid, fumaric acid, maleic acid, and glutaric acid. In organic acids containing multiple carboxylic acids (e.g., from two to four carboxylic acid groups), one or more of the carboxylic acid groups may be esterified. Non-limiting examples include succinic acid monoethyl ester, monomethyl fumarate, monomethyl or dimethyl citrate, and the like.

In some embodiments, the organic acid may include more than one carboxylic acid group and one or more hydroxyl groups. Non-limiting examples of such acids include tartaric acid, citric acid, and the like.

In some embodiments, the organic acid is an aryl carboxylic acid or an aryl sulfonic acid. Non-limiting examples of aryl carboxylic and sulfonic acids include benzoic acid, toluic acids, salicylic acid, benzenesulfonic acid,and *p*-toluenesulfonic acid.

Further non-limiting examples of organic acids which may be useful in certain embodiments include 2,2-dichloroacetic acid, 2-hydroxyethanesulfonic acid, 2-oxoglutaric acid, 4-acetamidobenzoic acid, 4-aminosalicylic acid, adipic acid, ascorbic acid (L), aspartic acid (L), alpha-methylbutyric acid, camphoric acid (+), camphor-10-sulfonic acid (+), cinnamic acid, cyclamic acid, dodecylsulfuric acid, ethane-1,2-disulfonic acid, ethanesulfonic acid, furoic acid, galactaric acid, gentisic acid, glucoheptonic acid, gluconic acid, glucuronic acid, glutamic acid, glycerophosphoric acid, glycolic acid, hippuric acid, isobutyric acid, isovaleric acid, lactobionic acid, lauric acid, levulinic acid, malic acid, malonic acid, mandelic acid, methanesulfonic acid, naphthalene-1,5-disulfonic acid, naphthalene-2-sulfonic acid, oleic acid, palmitic acid, pamoic acid, phenylacetic acid, pyroglutamic acid, pyruvic acid, sebacic acid, stearic acid, and undecylenic acid.

Examples of suitable acids include, but are not limited to, the list of organic acids in Table 1.

Table 1. Non-limiting examples of suitable organic acids

Acid Name	logP
benzoic acid	1.9
phenylacetic	1.4
p-toluic acid	2.3

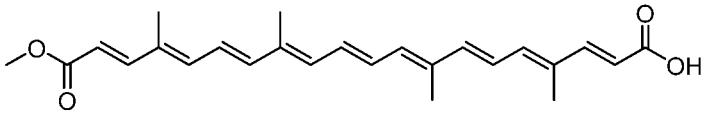
Acid Name	logP
ethyl benzoic acid	2.9
isopropyl benzoic acid	3.5
4-phenylbutyric	2.4
2-napthoxyacetic acid	2.5
napthylacetic acid	2.7
heptanoic acid	2.5
octanoic acid	3.05
nonanoic acid	3.5
decanoic acid	4.09
9-deceneoic acid	3.3
2-deceneoic acid	3.8
10-undecenoic acid	3.9
dodecandioic acid	3.2
dodecanoic acid	4.6
myristic acid	5.3
palmitic acid	6.4
stearic acid	7.6
cyclohexanebutanoic acid	3.4
1-heptanesulfonic acid	2.0
1-octanesulfonic acid	2.5
1-nonanesulfonic acid	3.1
monooctyl succinate	2.8
tocopherol succinate	10.2
monomenthyl succinate	3
monomenthyl glutarate	3.4
norbixin ((2E,4E,6E,8E,10E,12E,14E,16E,18E)-4,8,13,17-tetramethylicosa-2,4,6,8,10,12,14,16,18-nonaenedioic acid)	7.2
bixin ((2E,4E,6E,8E,10E,12E,14E,16Z,18E)-20-methoxy-4,8,13,17-tetramethyl-20-oxoicosa-2,4,6,8,10,12,14,16,18-nonaenoic acid)	7.5

5

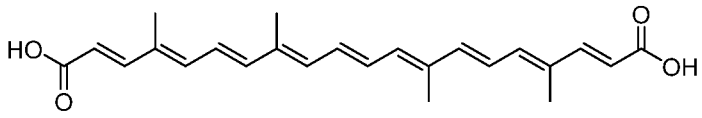
In some embodiments, the organic acid is a mono ester of a di- or poly-acid, such as mono-octyl succinate, mono-octyl fumarate, or the like. For example, in some embodiments, the organic acid is a mono ester of a dicarboxylic acid or a poly-carboxylic acid. In some embodiments, the dicarboxylic acid is malonic acid, succinic acid, glutaric acid, adipic acid, fumaric acid, maleic acid, or a combination thereof. In some embodiments, the dicarboxylic acid is succinic acid, glutaric acid, fumaric acid, maleic acid, or a combination thereof. In some embodiments, the dicarboxylic acid is succinic acid, glutaric acid, or a combination thereof.

In some embodiments, the alcohol forming the mono ester of the dicarboxylic acid is a lipophilic alcohol. Examples of suitable lipophilic alcohols include, but are not limited to, octanol, menthol, and tocopherol. In some embodiments, the organic acid is an octyl mono ester of a dicarboxylic acid, such as monooctyl succinate, monooctyl fumarate, or the like. In some embodiments, the organic acid is a monomenthyl ester of a dicarboxylic acid. Certain menthyl esters may be desirable in oral compositions as described herein by virtue of the cooling sensation they may provide upon use of the product comprising the composition. In some embodiments, the organic acid is monomenthyl succinate, monomenthyl fumarate, monomenthyl glutarate, or a combination thereof. In some embodiments, the organic acid is a monotocopheryl ester of a dicarboxylic acid. Certain tocopheryl esters may be desirable in oral compositions as described herein by virtue of the antioxidant effects they may provide. In some embodiments, the organic acid is tocopheryl succinate, tocopheryl fumarate, tocopheryl glutarate, or a combination thereof.

In some embodiments, the organic acid is a carotenoid derivative having one or more carboxylic acids. Carotenoids are tetraterpenes, meaning that they are produced from 8 isoprene molecules and contain 40 carbon atoms. Accordingly, they are usually lipophilic due to the presence of long unsaturated aliphatic chains, and are generally yellow, orange, or red in color. Certain carotenoid derivatives can be advantageous in oral compositions by virtue of providing both ion pairing and serving as a colorant in the composition. In some embodiments, the organic acid is 2*E*,4*E*,6*E*,8*E*,10*E*,12*E*,14*E*,16*Z*,18*E*)-20-methoxy-4,8,13,17-tetramethyl-20-oxoicosa-2,4,6,8,10,12,14,16,18-nonaenoic acid (bixin) or an isomer thereof. Bixin is an apocarotenoid found in annatto seeds from the achiote tree (*Bixa orellana*), and is the naturally occurring pigment providing the reddish orange color to annatto. Bixin is soluble in fats and alcohols but insoluble in water, and is chemically unstable when isolated, converting via isomerization into the double bond isomer, *trans*-bixin (β-bixin), having the structure:



In some embodiments, the organic acid is (2*E*,4*E*,6*E*,8*E*,10*E*,12*E*,14*E*,16*E*,18*E*)-4,8,13,17-tetramethylicosa-2,4,6,8,10,12,14,16,18-nonaenedioic acid (norbixin), a water soluble hydrolysis product of bixin having the structure:



The selection of organic acid may further depend on additional properties in addition to or without consideration to the logP value. For example, an organic acid should be one recognized as safe for human consumption, and which has acceptable flavor, odor, volatility, stability, and the like. Determination of appropriate organic acids is within the purview of one of skill in the art.

In some embodiments, the organic acid is benzoic acid, a toluic acid, benzenesulfonic acid, toluenesulfonic acid, hexanoic acid, heptanoic acid, decanoic acid, or octanoic acid. In some embodiments, the organic acid is benzoic acid, octanoic acid, or decanoic acid. In some embodiments, the organic acid is octanoic acid. In some embodiments, the organic acid is benzoic acid.

In some embodiments, more than one organic acid may be present. For example, the composition may comprise two, or three, or four, or more organic acids. Accordingly, reference herein to "an organic acid" contemplates mixtures of two or more organic acids. The relative amounts of the multiple organic acids may vary. For example, a composition may comprise equal amounts of two, or three, or more organic acids, or may comprise different relative amounts. In this manner, it is possible to include certain organic acids (e.g., citric acid or myristic acid) which have a logP value outside the desired range, when combined with other organic acids to provide the desired average logP range for the combination. In some embodiments, it may be desirable to include organic acids in the composition which have logP values outside the desired range for purposes such as, but not limited to, providing desirable organoleptic properties, stability, as flavor components, and the like. Further, certain lipophilic organic acids have undesirable flavor and or aroma characteristics which would preclude their presence as the sole organic acid (e.g., in equimolar or greater quantities relative to nicotine). Without wishing to be bound by theory, it is believed that a combination of different organic acids may provide desirable ion pairing while the concentration of any single organic acid in the composition remains below the threshold which would be found objectionable from a sensory perspective. For example, in some embodiments, the organic acid may comprise from about 1 to about 5 or more molar equivalents of benzoic acid relative to the basic amine-containing active ingredient (e.g., nicotine), combined with e.g., about 0.2 molar equivalents of octanoic acid or a salt thereof, and 0.2 molar equivalents of decanoic acid or a salt thereof.

In some embodiments, the organic acid is a combination of any two organic acids selected from the group consisting of benzoic acid, a toluic acid, benzenesulfonic acid, toluenesulfonic acid, hexanoic acid, heptanoic acid, decanoic acid, and octanoic acid. In some embodiments, the organic

acid is a combination of benzoic acid, octanoic acid, and decanoic acid, or benzoic and octanoic acid. In some embodiments, the composition comprises citric acid in addition to one or more of benzoic acid, a toluic acid, benzenesulfonic acid, toluenesulfonic acid, hexanoic acid, heptanoic acid, decanoic acid, and octanoic acid.

In some embodiments, the composition comprises an alkali metal salt of an organic acid. For example, at least a portion of the organic acid may be present in the composition in the form of an alkali metal salt. Suitable alkali metals include lithium, sodium, and potassium. In some embodiments, the alkali metal is sodium or potassium. In some embodiments, the alkali metal is sodium. In some embodiments, the composition comprises an organic acid and a sodium salt of the organic acid.

In some embodiments, the composition comprises benzoic acid and sodium benzoate, octanoic acid and sodium octanoate, decanoic acid and sodium decanoate, or a combination thereof. In some embodiments, the composition comprises benzoic acid and sodium benzoate. In some embodiments, the composition comprises sodium benzoate. In some embodiments, the ratio of the organic acid to the sodium salt of the organic acid is from about 0.1 to about 10, such as from about 0.1, about 0.25, about 0.3, about 0.5, about 0.75, or about 1, to about 2, about 5, or about 10. For example, in some embodiments, both an organic acid and the sodium salt thereof are added to the other components of the composition, wherein the organic acid is added in excess of the sodium salt, in equimolar quantities with the sodium salt, or as a fraction of the sodium salt. One of skill in the art will recognize that the relative amounts will be determined by the desired pH of the composition, as well as the desired ionic strength. For example, the organic acid may be added in a quantity to provide a desired pH level of the composition, while the alkali metal (e.g., sodium) salt is added in a quantity to provide the desired extent of ion pairing. As one of skill in the art will understand, the quantity of organic acid (i.e., the protonated form) present in the composition, relative to the alkali metal salt or conjugate base form present in the composition, will vary according to the pH of the composition and the pKa of the organic acid, as well as according to the actual relative quantities initially added to the composition.The amount of organic acid or an alkali metal salt thereof present in the composition, relative to the basic amine-containing active ingredient (e.g., nicotine), may vary. Generally, as the concentration of the organic acid (or the conjugate base thereof) increases, the percent of basic amine-containing active ingredient (e.g., nicotine) that is ion paired with the organic acid increases. This typically increases the partitioning of the basic amine-containing active ingredient (e.g., nicotine), in the form of an ion pair, into octanol versus water as measured by the logP (the $\log_{10}$ of the partitioning coefficient). In some embodiments, the composition comprises from about 0.05, about 0.1, about 1, about 1.5, about 2, or about 5, to about 10, about 15, or about 20 molar equivalents of the organic acid, the alkali metal salt thereof, or the combination thereof, relative to the basic amine-containing active ingredient (e.g., nicotine), calculated as the free base amine-containing active ingredient.

In some embodiments, the composition comprises from about 2 to about 10, or from about 2 to about 5 molar equivalents of the organic acid, the alkali metal salt thereof, or the combination thereof, to nicotine, on a free-base nicotine basis. In some embodiments, the organic acid, the alkali metal salt thereof, or the combination thereof, is present in a molar ratio with the basic amine-containing active ingredient (e.g., nicotine) from about 1, about 2, about 3, about 4, or about 5, to about 6, about 7, about 8, about 9, or about 10. In embodiments wherein more than one organic acid, alkali metal salt thereof, or both, are present, it is to be understood that such molar ratios reflect the totality of the organic acids present.

In certain embodiments the organic acid inclusion is sufficient to provide a composition pH of from about 3.0 to about 9.5, such as from about 3.0 to about 9.0, or from about 3.0 to about 8.5, or from about 3.0 to about 8.0, or from about 3.5 to about 7.5, or from about 4.5 to about 7.0, or from about 5.5 to about 7.0, or from about 4.0 to about 5.5, or from about 7.0 to about 9.5. In some embodiments, the organic acid inclusion is sufficient to provide a composition pH of about 3.0, about 3.5, about 4.0, about 4.5, about 5.0, about 5.5, about 6.0, about 6.5, about 7.0, about 7.5, about 8.0, about 8.5, or about 9.0. In some embodiments, the organic acid inclusion is sufficient to provide a composition pH of from about 4.5 to about 6.5, for example, from about 4.5, about 5.0, or about 5.5, to about 6.0, or about 6.5. In some embodiments, the organic acid is provided in a quantity sufficient to provide a pH of the composition of from about 5.5 to about 6.5, for example, from about 5.5, about 5.6, about 5.7, about 5.8, about 5.9, or about 6.0, to about 6.1, about 6.2, about 6.3, about 6.4, or about 6.5. In other embodiments, a mineral acid (e.g., hydrochloric acid, sulfuric acid, phosphoric acid, or the like) is added to adjust the pH of the composition to the desired value. Notably, at alkaline pH values (e.g., such as from about 7.5 to about 9), nicotine is largely present in the free base form (and accordingly, exhibits high partitioning into octanol), while, at acidic pH values (such as from about 6.5 to about 4), nicotine is largely present in a protonated form (and accordingly, exhibits lower partitioning into octanol). In some embodiments, a buffer, such as carbonate or bicarbonate, are added to adjust and/or maintain the desired pH value. Other suitable buffers are described further herein below.

In some embodiments, the organic acid is added as the free acid, either neat (i.e., native solid or liquid form) or as a solution in, e.g., water, to the other composition components. In some embodiments, the alkali metal salt of the organic acid is added, either neat or as a solution in, e.g., water, to the other composition components. In some embodiments, the organic acid and the basic amine-containing active ingredient (e.g., nicotine) are combined to form a salt, either before addition to the composition, or the salt is formed within and is present in the composition as such. In other embodiments, the organic acid and basic amine-containing active ingredient (e.g., nicotine) are present as individual components in the composition, and form an ion pair upon contact with moisture (e.g., saliva in the mouth of the consumer).

In some embodiments, the composition further comprises a solubility enhancer to increase the solubility of one or more of the organic acid or salt thereof. Suitable solubility enhancers include, but are not limited to, humectants as described herein such as glycerin or propylene glycol.

Buffering agents

In certain embodiments, the composition of the present disclosure can comprise pH adjusters or buffering agents. Examples of pH adjusters and buffering agents that can be used include, but are not limited to, metal hydroxides (e.g., alkali metal hydroxides such as sodium hydroxide and potassium hydroxide), and other alkali metal buffers such as metal carbonates (e.g., potassium carbonate or sodium carbonate), or metal bicarbonates such as sodium bicarbonate, and the like. Non-limiting examples of suitable buffers include alkali metals acetates, glycinates, phosphates, glycerophosphates, citrates, carbonates, hydrogen carbonates, borates, or mixtures thereof. In some embodiments, the buffer is sodium bicarbonate. In some embodiments, the buffer is sodium carbonate.

Where present, the buffering agent is typically present in an amount less than about 5% by weight, based on the weight of the composition, for example, from about 0.1% to about 5%, such as, *e.g.,* from about 0.1% to about 1%, or from about 0.1% to about 0.5% by weight, based on the total weight of the composition.

Colorants

A colorant may be employed in amounts sufficient to provide the desired physical attributes to the composition. Examples of colorants include various dyes and pigments, such as caramel coloring and titanium dioxide. The amount of colorant utilized in the composition can vary, but when present is typically up to about 3% by weight, such as from about 0.1%, about 0.5%, or about 1%, to about 3% by weight, based on the total weight of the composition.

Tobacco material

In some embodiments, the composition may include a tobacco material. The tobacco material can vary in species, type, and form. Generally, the tobacco material is obtained from for a harvested plant of the *Nicotiana* species. Example *Nicotiana* species include N. tabacum, N. rustica, N. alata, N. arentsii, N. excelsior, N. forgetiana, N. glauca, N. glutinosa, N. gossei, N. kawakamii, N. knightiana, N. langsdorffi, N. otophora, N. setchelli, N. sylvestris, N. tomentosa, N. tomentosiformis, N. undulata, N. x sanderae, N. africana, N. amplexicaulis, N. benavidesii, N. bonariensis, N. debneyi, N. longiflora, N. maritina, N. megalosiphon, N. occidentalis, N. paniculata, N. plumbaginifolia, N. raimondii, N. rosulata, N. simulans, N. stocktonii, N. suaveolens, N. umbratica, N. velutina, N. wigandioides, N. acaulis, N. acuminata, N. attenuata, N. benthamiana, N. cavicola, N. clevelandii, N. cordifolia, N. corymbosa, N. fragrans, N. goodspeedii, N. linearis, N. miersii, N. nudicaulis, N.

obtusifolia, N. occidentalis subsp. Hersperis, N. pauciflora, N. petunioides, N. quadrivalvis, N. repanda, N. rotundifolia, N. solanifolia, and N. spegazzinii. Various representative other types of plants from the *Nicotiana* species are set forth in Goodspeed, *The Genus Nicotiana*, (Chonica Botanica) (1954); US Pat. Nos. 4,660,577 to Sensabaugh, Jr. et al.; 5,387,416 to White et al., 7,025,066 to Lawson et al.; 7,798,153 to Lawrence, Jr. and 8,186,360 to Marshall et al.; each of which is incorporated herein by reference. Descriptions of various types of tobaccos, growing practices and harvesting practices are set forth in *Tobacco Production, Chemistry and Technology*, Davis et al. (Eds.) (1999), which is incorporated herein by reference.

Nicotiana species from which suitable tobacco materials can be obtained can be derived using genetic-modification or crossbreeding techniques (e.g., tobacco plants can be genetically engineered or crossbred to increase or decrease production of components, characteristics or attributes). See, for example, the types of genetic modifications of plants set forth in US Pat. Nos. 5,539,093 to Fitzmaurice et al.; 5,668,295 to Wahab et al.; 5,705,624 to Fitzmaurice et al.; 5,844,119 to Weigl; 6,730,832 to Dominguez et al.; 7,173,170 to Liu et al.; 7,208,659 to Colliver et al. and 7,230,160 to Benning et al.; US Patent Appl. Pub. No. 2006/0236434 to Conkling et al.; and PCT WO2008/103935 to Nielsen et al. See, also, the types of tobaccos that are set forth in US Pat. Nos. 4,660,577 to Sensabaugh, Jr. et al.; 5,387,416 to White et al.; and 6,730,832 to Dominguez et al., each of which is incorporated herein by reference.

The *Nicotiana* species can, in some embodiments, be selected for the content of various compounds that are present therein. For example, plants can be selected on the basis that those plants produce relatively high quantities of one or more of the compounds desired to be isolated therefrom. In certain embodiments, plants of the *Nicotiana* species (e.g., *Galpao commun* tobacco) are specifically grown for their abundance of leaf surface compounds. Tobacco plants can be grown in greenhouses, growth chambers, or outdoors in fields, or grown hydroponically.

Various parts or portions of the plant of the *Nicotiana* species can be included within a composition as disclosed herein. For example, virtually all of the plant (*e.g.*, the whole plant) can be harvested, and employed as such. Alternatively, various parts or pieces of the plant can be harvested or separated for further use after harvest. For example, the flower, leaves, stem, stalk, roots, seeds, and various combinations thereof, can be isolated for further use or treatment. In some embodiments, the tobacco material comprises tobacco leaf (lamina). The composition disclosed herein can include processed tobacco parts or pieces, cured and aged tobacco in essentially natural lamina and/or stem form, a tobacco extract, extracted tobacco pulp (e.g., using water as a solvent), or a mixture of the foregoing (e.g., a mixture that combines extracted tobacco pulp with granulated cured and aged natural tobacco lamina).

In certain embodiments, the tobacco material comprises solid tobacco material selected from the group consisting of lamina and stems. The tobacco that is used for the mixture most preferably

includes tobacco lamina, or a tobacco lamina and stem mixture (of which at least a portion is smoke-treated). Portions of the tobaccos within the mixture may have processed forms, such as processed tobacco stems (e.g., cut-rolled stems, cut-rolled-expanded stems or cut-puffed stems), or volume expanded tobacco (e.g., puffed tobacco, such as dry ice expanded tobacco (DIET)). See, for example, the tobacco expansion processes set forth in US Pat. Nos. 4,340,073 to de la Burde et al.; 5,259,403 to Guy et al.; and 5,908,032 to Poindexter, et al.; and 7,556,047 to Poindexter, et al., all of which are incorporated by reference. In addition, the d mixture optionally may incorporate tobacco that has been fermented. See, also, the types of tobacco processing techniques set forth in PCT WO2005/063060 to Atchley et al., which is incorporated herein by reference.

The tobacco material is typically used in a form that can be described as particulate (i.e., shredded, ground, granulated, or powder form). The manner by which the tobacco material is provided in a finely divided or powder type of form may vary. Preferably, plant parts or pieces are comminuted, ground or pulverized into a particulate form using equipment and techniques for grinding, milling, or the like. Most preferably, the plant material is relatively dry in form during grinding or milling, using equipment such as hammer mills, cutter heads, air control mills, or the like. For example, tobacco parts or pieces may be ground or milled when the moisture content thereof is less than about 15% by weight, or less than about % by weight. Most preferably, the tobacco material is employed in the form of parts or pieces that have an average particle size between 1.4 millimeters and 250 microns. In some instances, the tobacco particles may be sized to pass through a screen mesh to obtain the particle size range required. If desired, air classification equipment may be used to ensure that small sized tobacco particles of the desired sizes, or range of sizes, may be collected. If desired, differently sized pieces of granulated tobacco may be mixed together.

The manner by which the tobacco is provided in a finely divided or powder type of form may vary. Preferably, tobacco parts or pieces are comminuted, ground or pulverized into a powder type of form using equipment and techniques for grinding, milling, or the like. Most preferably, the tobacco is relatively dry in form during grinding or milling, using equipment such as hammer mills, cutter heads, air control mills, or the like. For example, tobacco parts or pieces may be ground or milled when the moisture content thereof is less than about 15% by weight to less than about 5% by weight. For example, the tobacco plant or portion thereof can be separated into individual parts or pieces (e.g., the leaves can be removed from the stems, and/or the stems and leaves can be removed from the stalk). The harvested plant or individual parts or pieces can be further subdivided into parts or pieces (e.g., the leaves can be shredded, cut, comminuted, pulverized, milled or ground into pieces or parts that can be characterized as filler-type pieces, granules, particulates or fine powders). The plant, or parts thereof, can be subjected to external forces or pressure (e.g., by being pressed or subjected to roll treatment). When carrying out such processing conditions, the plant or portion thereof can have a moisture content that approximates its natural moisture content (e.g., its moisture content immediately

upon harvest), a moisture content achieved by adding moisture to the plant or portion thereof, or a moisture content that results from the drying of the plant or portion thereof. For example, powdered, pulverized, ground or milled pieces of plants or portions thereof can have moisture contents of less than about 25% by weight, often less than about 20%, and frequently less than about 15% by weight.

For the preparation of oral products, it is typical for a harvested plant of the *Nicotiana* species to be subjected to a curing process. The tobacco materials incorporated within the mixture for inclusion within products as disclosed herein are those that have been appropriately cured and/or aged. Descriptions of various types of curing processes for various types of tobaccos are set forth in *Tobacco Production, Chemistry and Technology,* Davis et al. (Eds.) (1999). Examples of techniques and conditions for curing flue-cured tobacco are set forth in Nestor et al., *Beitrage Tabakforsch. Int.,* 20, 467-475 (2003) and US Pat. No. 6,895,974 to Peele, which are incorporated herein by reference. Representative techniques and conditions for air curing tobacco are set forth in US Pat. No. 7,650,892 to Groves et al.; Roton et al., *Beitrage Tabakforsch. Int.,* 21, 305-320 (2005) and Staaf et al., *Beitrage Tabakforsch. Int.,* 21, 321-330 (2005), which are incorporated herein by reference. Certain types of tobaccos can be subjected to alternative types of curing processes, such as fire curing or sun curing.

In certain embodiments, tobacco materials that can be employed include flue-cured or Virginia (e.g., K326), burley, sun-cured (e.g., Indian Kurnool and Oriental tobaccos, including Katerini, Prelip, Komotini, Xanthi and Yambol tobaccos), Maryland, dark, dark-fired, dark air cured (e.g., Madole, Passanda, Cubano, Jatin and Bezuki tobaccos), light air cured (e.g., North Wisconsin and Galpao tobaccos), Indian air cured, Red Russian and *Rustica* tobaccos, as well as various other rare or specialty tobaccos and various blends of any of the foregoing tobaccos.

The tobacco material may also have a so-called "blended" form. For example, the tobacco material may include a mixture of parts or pieces of flue-cured, burley (e.g., Malawi burley tobacco) and Oriental tobaccos (e.g., as tobacco composed of, or derived from, tobacco lamina, or a mixture of tobacco lamina and tobacco stem). For example, a representative blend may incorporate about 30 to about 70 parts burley tobacco (e.g., lamina, or lamina and stem), and about 30 to about 70 parts flue cured tobacco (e.g., stem, lamina, or lamina and stem) on a dry weight basis. Other example tobacco blends incorporate about 75 parts flue-cured tobacco, about 15 parts burley tobacco, and about 10 parts Oriental tobacco; or about 65 parts flue-cured tobacco, about 25 parts burley tobacco, and about 10 parts Oriental tobacco; or about 65 parts flue-cured tobacco, about 10 parts burley tobacco, and about 25 parts Oriental tobacco; on a dry weight basis. Other example tobacco blends incorporate about 20 to about 30 parts Oriental tobacco and about 70 to about 80 parts flue-cured tobacco on a dry weight basis.

Tobacco materials used in the present disclosure can be subjected to, for example, fermentation, bleaching, and the like. If desired, the tobacco materials can be, for example, irradiated, pasteurized, or otherwise subjected to controlled heat treatment. Such treatment processes are

detailed, for example, in US Pat. No. 8,061,362 to Mua et al., which is incorporated herein by reference. In certain embodiments, tobacco materials can be treated with water and an additive capable of inhibiting reaction of asparagine to form acrylamide upon heating of the tobacco material (e.g., an additive selected from the group consisting of lysine, glycine, histidine, alanine, methionine, cysteine, glutamic acid, aspartic acid, proline, phenylalanine, valine, arginine, compositions incorporating di- and trivalent cations, asparaginase, certain non-reducing saccharides, certain reducing agents, phenolic compounds, certain compounds having at least one free thiol group or functionality, oxidizing agents, oxidation catalysts, natural plant extracts (e.g., rosemary extract), and combinations thereof. See, for example, the types of treatment processes described in US Pat. Pub. Nos. 8,434,496, 8,944,072, and 8,991,403 to Chen et al., which are all incorporated herein by reference. In certain embodiments, this type of treatment is useful where the original tobacco material is subjected to heat in the processes previously described.

In various embodiments, the tobacco material can be treated to extract a soluble component of the tobacco material therefrom. "Tobacco extract" as used herein refers to the isolated components of a tobacco material that are extracted from solid tobacco pulp by a solvent that is brought into contact with the tobacco material in an extraction process. Various extraction techniques of tobacco materials can be used to provide a tobacco extract and tobacco solid material. See, for example, the extraction processes described in US Pat. Appl. Pub. No. 2011/0247640 to Beeson et al., which is incorporated herein by reference. Other example techniques for extracting components of tobacco are described in US Pat. Nos. 4,144,895 to Fiore; 4,150,677 to Osborne, Jr. et al.; 4,267,847 to Reid; 4,289,147 to Wildman et al.; 4,351,346 to Brummer et al.; 4,359,059 to Brummer et al.; 4,506,682 to Muller; 4,589,428 to Keritsis; 4,605,016 to Soga et al.; 4,716,911 to Poulose et al.; 4,727,889 to Niven, Jr. et al.; 4,887,618 to Bernasek et al.; 4,941,484 to Clapp et al.; 4,967,771 to Fagg et al.; 4,986,286 to Roberts et al.; 5,005,593 to Fagg et al.; 5,018,540 to Grubbs et al.; 5,060,669 to White et al.; 5,065,775 to Fagg; 5,074,319 to White et al.; 5,099,862 to White et al.; 5,121,757 to White et al.; 5,131,414 to Fagg; 5,131,415 to Munoz et al.; 5,148,819 to Fagg; 5,197,494 to Kramer; 5,230,354 to Smith et al.; 5,234,008 to Fagg; 5,243,999 to Smith; 5,301,694 to Raymond et al.; 5,318,050 to Gonzalez-Parra et al.; 5,343,879 to Teague; 5,360,022 to Newton; 5,435,325 to Clapp et al.; 5,445,169 to Brinkley et al.; 6,131,584 to Lauterbach; 6,298,859 to Kierulff et al.; 6,772,767 to Mua et al.; and 7,337,782 to Thompson, all of which are incorporated by reference herein.

In some embodiments, the type of tobacco material is selected such that it is initially visually lighter in color than other tobacco materials to some degree (e.g., whitened or bleached). Tobacco pulp can be whitened in certain embodiments according to any means known in the art, and as described above in reference to color-eliminated active ingredients.

Typical inclusion ranges for tobacco materials can vary depending on the nature and type of the tobacco material, and the intended effect on the final composition, with an example range of up to

about 30% by weight (or up to about 20% by weight or up to about 10% by weight or up to about 5% by weight), based on total weight of the composition (e.g., about 0.1 to about 15% by weight). In some embodiments, the products of the disclosure can be characterized as completely free or substantially free of tobacco material (other than purified nicotine as an active ingredient). For example, certain embodiments can be characterized as having less than 1% by weight, or less than 0.5% by weight, or less than 0.1% by weight of tobacco material, or less than 0.01% by weight of tobacco material, or 0% by weight of tobacco material.

Oral care additives

In some embodiments, the composition comprises an oral care ingredient (or mixture of such ingredients). Oral care ingredients provide the ability to inhibit tooth decay or loss, inhibit gum disease, relieve mouth pain, whiten teeth, or otherwise inhibit tooth staining, elicit salivary stimulation, inhibit breath malodor, freshen breath, or the like. For example, effective amounts of ingredients such as thyme oil, eucalyptus oil and zinc (e.g., such as the ingredients of formulations commercially available as ZYTEX® from Discus Dental) can be incorporated into the composition. Other examples of ingredients that can be incorporated in desired effective amounts within the present composition can include those that are incorporated within the types of oral care compositions set forth in Takahashi et al., Oral Microbiology and Immunology, 19(1), 61-64 (2004); U.S. Pat. No. 6,083,527 to Thistle; and US Pat. Appl. Pub. Nos. 2006/0210488 to Jakubowski and 2006/02228308 to Cummins et al. Other exemplary ingredients of tobacco containing-formulation include those contained in formulations marketed as MALTISORB® by Roquette and DENTIZYME® by NatraRx. When present, a representative amount of oral care additive is at least about 1%, often at least about 3%, and frequently at least about 5% of the total dry weight of the composition. The amount of oral care additive within the composition will not typically exceed about 30%, often will not exceed about 25%, and frequently will not exceed about 20%, of the total dry weight of the composition.

Processing aids

If necessary for downstream processing of ingredients of the product, such as granulation or mixing, or of the product itself, such as tableting, a processing aid (e.g., a flow aid) can also be included among the product ingredients in order to enhance e.g., flowability or compression of ingredients. Example processing aids include microcrystalline cellulose, silica, polyethylene glycol, stearic acid, calcium stearate, magnesium stearate, zinc stearate, sodium stearyl fumarate, canauba wax, and combinations thereof. In some embodiments, the processing aid is a flow aid or lubricant. In some embodiments, the flow aid or lubricant is silica, stearic acid, magnesium stearate, sodium stearyl fumarate, or a combination thereof.

When present, a representative amount of processing aid may make up at least about 0.5 percent or at least about 1 percent of the total weight of the product. Preferably, the amount of processing aid within the product will not exceed about 5 percent, and frequently will not exceed about 3 percent of the total weight of the product.

Other additives

Other additives can be included in the disclosed composition. For example, the composition can be processed, blended, formulated, combined, and/or mixed with other materials or ingredients. The additives can be artificial, or can be obtained or derived from herbal or biological sources. Examples of further types of additives include thickening or gelling agents (e.g., fish gelatin), emulsifiers, preservatives (e.g., potassium sorbate and the like), disintegration aids, zinc or magnesium salts selected to be relatively water soluble for compositions with greater water solubility (e.g., magnesium or zinc gluconate) or selected to be relatively water insoluble for compositions with reduced water solubility (e.g., magnesium or zinc oxide), or combinations thereof. See, for example, those representative components, combination of components, relative amounts of those components, and manners and methods for employing those components, set forth in US Pat. No. 9,237,769 to Mua et al., US Pat. No. 7,861,728 to Holton, Jr. et al., US Pat. App. Pub. No. 2010/0291245 to Gao et al., and US Pat. App. Pub. No. 2007/0062549 to Holton, Jr. et al., each of which is incorporated herein by reference. Typical inclusion ranges for such additional additives can vary depending on the nature and function of the additive and the intended effect on the final composition, with an example range of up to about 10% by weight, based on total weight of the composition (e.g., about 0.1 to about 5% by weight).

The aforementioned additives can be employed together (e.g., as additive formulations) or separately (e.g., individual additive components can be added at different stages involved in the preparation of the final composition). Furthermore, the aforementioned types of additives may be encapsulated as provided in the final product or composition. Exemplary encapsulated additives are described, for example, in WO2010/132444 to Atchley, which has been previously incorporated by reference herein.

Particulate

In some embodiments, any one or more component of the composition, or the composition as a whole, can be described as a particulate material or as in particulate form. As used herein, the term "particulate" refers to a material in the form of a plurality of individual particles, some of which can be in the form of an agglomerate of multiple particles, wherein the particles have an average length to width ratio less than 2:1, such as less than 1.5:1, such as about 1:1. In various embodiments, the particles of a particulate material can be described as substantially spherical or granular.

The particle size of a particulate material may be measured by sieve analysis. As the skilled person will readily appreciate, sieve analysis (otherwise known as a gradation test) is a method used to measure the particle size distribution of a particulate material. Typically, sieve analysis involves a nested column of sieves which comprise screens, preferably in the form of wire mesh cloths. A pre-weighed sample may be introduced into the top or uppermost sieve in the column, which has the largest screen openings or mesh size (i.e. the largest pore diameter of the sieve). Each lower sieve in the column has progressively smaller screen openings or mesh sizes than the sieve above. Typically, at the base of the column of sieves is a receiver portion to collect any particles having a particle size smaller than the screen opening size or mesh size of the bottom or lowermost sieve in the column (which has the smallest screen opening or mesh size).

In some embodiments, the column of sieves may be placed on or in a mechanical agitator. The agitator causes the vibration of each of the sieves in the column. The mechanical agitator may be activated for a pre-determined period of time in order to ensure that all particles are collected in the correct sieve. In some embodiments, the column of sieves is agitated for a period of time from 0.5 minutes to 10 minutes, such as from 1 minute to 10 minutes, such as from 1 minute to 5 minutes, such as for approximately 3 minutes. Once the agitation of the sieves in the column is complete, the material collected on each sieve is weighed. The weight of each sample on each sieve may then be divided by the total weight in order to obtain a percentage of the mass retained on each sieve. As the skilled person will readily appreciate, the screen opening sizes or mesh sizes for each sieve in the column used for sieve analysis may be selected based on the granularity or known maximum/minimum particle sizes of the sample to be analysed. In some embodiments, a column of sieves may be used for sieve analysis, wherein the column comprises from 2 to 20 sieves, such as from 5 to 15 sieves. In some embodiments, a column of sieves may be used for sieve analysis, wherein the column comprises 10 sieves. In some embodiments, the largest screen opening or mesh sizes of the sieves used for sieve analysis may be 2000 μm, such as 1500 μm, such as 1000 μm, or such as 500 μm.

In some embodiments, any material referenced herein (*e.g.*, fillers, active ingredient, and the overall composition) characterized as being in particulate form may have at least 50% by weight of particles with a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 60% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 70% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 80% by weight of the particles of any particulate material

referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 90% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 95% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, at least 99% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm. In some embodiments, approximately 100% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of no greater than about 2000 μm, such as no greater than about 1500 μm, such as no greater than about 700 μm.

In some embodiments, at least 50% by weight, such as at least 60% by weight, such as at least 70% by weight, such as at least 80% by weight, such as at least 90% by weight, such as at least 95% by weight, such as at least 99% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of from about 0.01 μm to about 2000 μm, such as from about 0.05 μm to about 1500 μm, such as from about 0.1 μm to about 750 μm μm. In some embodiments, at least 50% by weight, such as at least 60% by weight, such as at least 70% by weight, such as at least 80% by weight, such as at least 90% by weight, such as at least 95% by weight, such as at least 99% by weight of the particles of any particulate material referenced herein have a particle size as measured by sieve analysis of from about 700 μm to about 2000 μm, such as from about 700 μm to about 1500 μm.

Configured for oral use

Provided herein is pouched product comprising a composition configured for oral use. The term "configured for oral use" as used herein means that the composition is provided in a form such that during use, saliva in the mouth of the user causes one or more of the components of the composition (e.g., flavoring agents and/or active ingredients) to pass into the mouth of the user. In certain embodiments, the composition is configured to deliver components to a user through mucous membranes in the user's mouth, the user's digestive system, or both, and, in some instances, said component is an active ingredient (including, but not limited to, for example, a stimulant, vitamin, taste modifier, or combination thereof) that can be absorbed through the mucous membranes in the mouth or absorbed through the digestive tract when the product is used.

In some embodiments, compositions configured for oral use as described herein comprise the composition of the present disclosure disposed within a moisture-permeable container (e.g., a water-

permeable pouch). Such compositions in the water-permeable pouch format are typically used by placing one pouch containing the composition in the mouth of a human subject/user. Generally, the pouch is placed somewhere in the oral cavity of the user, for example under the lips, in the same way as moist snuff products are generally used. The pouch preferably is not chewed or swallowed. Exposure to saliva then causes some of the components of the composition therein (e.g., flavoring agents and/or active ingredients) to pass through e.g., the water-permeable pouch and provide the user with flavor and satisfaction. After about 5 minutes to about 60 minutes, typically about 10 minutes to about 30 minutes, of use/enjoyment, substantial amounts of the composition have been released and absorbed through oral mucosa of the human subject, and the pouch may be removed from the mouth of the human subject for disposal.

The composition of the present disclosure is at least partially dissolvable. As used herein, the terms "dissolve," "dissolving," and "dissolvable" refer to compositions having aqueous-soluble components that interact with moisture in the oral cavity and enter into solution, thereby causing gradual consumption of the composition. In various embodiments, the composition can be adapted to or configured to at least partially dissolve or to completely dissolve in the oral cavity over a period of time. In some embodiments, the dissolvable composition is capable of lasting in the user's mouth for a given period of time until it substantially completely or completely dissolves. Dissolution rates can vary over a wide range, from about 1 minute or less to about 60 minutes. For example, fast release compositions typically dissolve and/or release the desired component(s) (e.g., active ingredient, flavor, and the like) in about 2 minutes or less, often about 1 minute or less (e.g., about 50 seconds or less, about 40 seconds or less, about 30 seconds or less, or about 20 seconds or less). In some embodiments, the dissolution rate is more gradual, such as dissolving and/or releasing the desired component(s) (e.g., active ingredient, flavor, and the like) over a period of time of about 60 minutes or less, such as about 45 minutes, about 30 minutes, or about 15 minutes. The dissolution rate may vary depending on such factors as the size, density, and surface area of the composition present within the pouch, as well as the quantity of composition by weight present within the pouch. Further, the dissolution rate and extent of dissolution may vary depending on the choice of filler and the solubility of other components present within the composition. Dissolution can occur by any means, such as melting, mechanical disruption (e.g., chewing), enzymatic or other chemical degradation, or by disruption of the interaction between the components of the composition.

In certain embodiments, the composition includes only saliva soluble materials, such that the composition completely dissolves in the oral cavity. In other embodiments, the composition further comprises insoluble components, such that a portion of the composition remains undissolved. In some embodiments, at least about 1% of the composition by weight dissolves in the oral cavity after a period of time of about 60 minutes or less, such as about 45 minutes, about 30 minutes, or about 15 minutes. In some embodiments, at least about 5%, at least about 10%, at least about 20%, at least

about 30%, at least about 40%, at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 95%, at least about 99%, or about 100% of the composition by weight dissolves in the oral cavity after a period of time of about 60 minutes or less, such as about 45 minutes, about 30 minutes, or about 15 minutes. In particular embodiments, at least about 95%, such as about 95%, about 96%, about 97%, about 98%, about 99%, or even 100% by weight of the composition dissolves in the oral cavity after a period of time of about 60 minutes or less, such as about 45 minutes, about 30 minutes, or about 15 minutes.

Compositions configured for oral use as described herein may take various forms, including pellets, tablets, granules, beads, and powders, any of which may be contained within a pouch. The compositions as disclosed herein can be formed into a variety of shapes, including pills, tablets, spheres, beads, ovoids, obloids, and the like. Cross-sectional shapes of the composition can vary, and example cross-sectional shapes include circles, squares, ovals, rectangles, and the like. Such shapes can be formed in a variety of manners using equipment such as moving belts, nips, extruders, granulation devices, compaction devices, and the like.

In some embodiments, the composition is in particulate form (e.g., powder or granular) enclosed within a pouch, and is substantially dissolved in less than about 10 minutes, such as from about 5 to about 10 minutes.

In some embodiments, the composition is in a beaded form (e.g., roughly spherical beads) enclosed within a pouch, and is substantially dissolved in less than about 30 minutes, such as from about 10 to about 15 minutes. In particular embodiments, the beads are configured to be substantially dissolvable (i.e., greater than 95%) in about 15 minutes or less. The rate of dissolution may vary based on the size of the beads and the specific filler utilized. The size of the beads may vary, but is generally from about 10 to about 25 mesh (from about 700 to about 2000 μm). Beaded embodiments generally comprise a large relative amount of a sugar alcohol as the dissolvable filler, such as isomalt. In some embodiments, the beaded composition comprises a humectant, such as glycerin or propylene glycol, in an amount up to about 25% by weight, such as from about 16 to about 20% by weight.

In some embodiments, the composition in beaded form can include an optional outer coating comprising a release modifying agent. Such release modifying agent coatings may provide for delayed and/or sustained release of components from the composition (e.g., flavorant, active ingredients, sweetener, dissolvable filler, and the like). The coating typically comprises a film-forming polymer, such as a cellulosic material, an optional plasticizer, and optional flavorants, colorants, salts, sweeteners or other additives of the types set forth herein. The coating compositions are usually aqueous in nature and can be applied using any coating technique known in the art, such as pan coating. Example film-forming polymers include cellulosic materials. Example plasticizers include aqueous solutions or emulsions of glyceryl monostearate and triethyl citrate. Additional potential coatings include food grade shellac, lipids, waxes, and combinations thereof. In some

embodiments, at least a portion of the beads are coated with a release modifying agent selected from the group consisting of lipids, cellulose derivatives, binders, and combinations thereof.

Non-limiting examples of suitable lipids include oils and waxes of natural (e.g., plant or animal based) or synthetic (e.g., petroleum derived) origin. Suitable lipids can be hydrogenated, partially hydrogenated, or non-hydrogenated. In some embodiments, the lipid is a food grade oil such as vegetable oils (e.g., acai oil, almond oil, amaranth oil, apricot oil, apple seed oil, argan oil, avocado oil, babassu oil, beech nut oil, ben oil, bitter gourd oil, black seed oil, blackcurrant seed oil, borage seed oil, borneo tallow nut oil, bottle gourd oil, brazil nut oil, buffalo gourd oil, butternut squash seed oil, cape chestnut oil, canola oil, carob cashew oil, cocoa butter, cocklebur oil, coconut oil, corn oil, cothune oil, coriander seed oil, cottonseed oil, date seed oil, dika oil, egus seed oil, evening primrose oil, false flax oil, flaxseed oil, grape seed oil, grapefruit seed oil, hazelnut oil, hemp oil, kapok seed oil, kenaf seed oil, lallemantia oil, lemon oil, linseed oil, macadamia oil, mafura oil, marula oil, meadowfoam seed oil, mongongo nut oil, mustard oil, niger seed oil, nutmeg butter, okra seed oil, olive oil, orange oil, palm oil, palm stearin, papaya seed oil, peanut oil, pecan oil, perilla seed oil, persimmon seed oil, pequi oil, pili nut oil, pine nut oil, pistachio oil, pomegranate seed oil, poppyseed oil, pracaxi oil, prune kernel oil, pumpkin seed oil, quinoa oil, ramtil oil, rapeseed oil, rice bran oil, royle oil, sacha inchi oil, safflower oil, sapote oil, seje oil, sesame oil, shea butter, soybean oil, sunflower oil, taramira oil, tea seed oil, thistle oil, tigernut oil, tobacco seed oil, tomato seed oil, walnut oil, watermelon seed oil, wheat germ oil, and combinations thereof), animal oils (e.g., cattle fat, buffalo fat, sheep fat, goat fat, pig fat, lard, camel fat, tallow, liquid margarine, fish oil, fish liver oil, whale oil, seal oil, and combinations thereof), and mineral oils. In some embodiments, the lipid is a wax, such as beeswax, carnauba, or paraffin wax.

Non-limiting examples of suitable cellulose derivatives include methylcellulose, hydroxypropylcellulose ("HPC"), hydroxypropylmethylcellulose ("HPMC"), hydroxyethyl cellulose, and carboxymethylcellulose ("CMC").

Non-limiting examples of suitable binders include povidone, alginate, starch-based binders, pectin, gums, carrageenan, pullulan, zein, and the like, and combinations thereof.

In some embodiments, the composition in beaded form comprises an optional outer coating comprising shellac, carnauba wax, paraffin wax, beeswax, palm oil, sunflower oil, or a combination thereof.

In some embodiments, mixtures of coated and uncoated beads are placed within a pouch. In some embodiments, mixtures of beads having different dissolution rates are placed within a pouch. For example, beads may be formed from different compositions (e.g., having different quantities of filler, or different types of filler) which dissolve at different rates in contact with saliva. In some embodiments, the pouch comprises the composition as disclosed herein in beaded form, and further comprises microcrystalline cellulose as a physical mixture with the beads. In some embodiments, a

flavor, an active ingredient, or both are present in or on the microcrystalline cellulose. In some embodiments, the microcrystalline cellulose comprises a liquid flavorant disposed thereon (i.e., adsorbed or absorbed in or on the microcrystalline cellulose). In some embodiments, the microcrystalline cellulose comprises a dry flavorant disposed thereon (i.e., adsorbed or absorbed in or on the microcrystalline cellulose). Embodiments with flavorant present in or on microcrystalline cellulose may be advantageous in providing a more homogenous product.

In some embodiments, the composition is in the form of one or more compressed or molded pellets (e.g., one or more tablets) enclosed within the pouch, and the composition is substantially dissolved in less than about 30 minutes, such as from about 20 to about 30 minutes. In some embodiments, the compressed or molded pellet within the pouch is subjected to a mechanical force prior to or when placed in the mouth of the user, such as breaking, crushing, or biting down on the pouched composition in order to increase the rate of dissolution of the composition and the individual components therein (e.g., flavorants, active ingredients, and the like). In some embodiments, a single compressed tablet or pellet is placed within a pouch. In some embodiments, multiple compressed tablets or pellets are placed within the pouch.

Certain embodiments of the disclosure will be described with reference to FIG. 1, and these described embodiments involve snus-type products having an outer pouch and containing the composition as described herein. Such embodiments are provided by way of example only. The composition/construction of such packets or pouches, such as the container pouch **102** in the embodiment illustrated in FIG. 1, may be varied as described herein above. Referring to FIG. 1, there is shown an embodiment of a pouched product **100**. The pouched product **100** includes a moisture-permeable container in the form of a pouch **102**, which contains a material **104** comprising the composition as described herein. Referring to FIG. 2, there is shown an embodiment of a pouched product **100** including a moisture-permeable container in the form of a pouch **102**, which contains the composition as described herein in tablet form **105**. Referring to FIG. 3, there is shown an embodiment of a pouched product **100** including a moisture-permeable container in the form of a pouch **102**, which contains the composition as described herein as powder, granules, multiple pellets, tablets, or beads **106**.

Pouches as described herein have three dimensions: a length, a width, and a thickness. One of skill in the art will recognize that such dimensions may vary depending on the intended overall size and volume of the pouch, and the quantity of material desired within the pouch. The amount of material contained within each pouch, may vary. In some embodiments, the weight of the composition within each pouch is at least about 50 mg, for example, from about 50 mg to about 2 grams, from about 100 mg to about 1.5 grams, or from about 200 to about 700 mg. In some smaller embodiments, the weight of the composition within each pouch may be from about 100 to about 300 mg. For a

larger embodiment, the weight of the material within each pouch may be from about 300 mg to about 700 mg.

If desired, other components can be contained within each pouch. For example, at least one flavored strip, piece or sheet of flavored water dispersible or water soluble material (e.g., a breath-freshening edible film type of material) may be disposed within each pouch along with or without at least one capsule. Such strips or sheets may be folded or crumpled in order to be readily incorporated within the pouch. See, for example, the types of materials and technologies set forth in US Pat. Nos. 6,887,307 to Scott et al. and 6,923,981 to Leung et al.; and The EFSA Journal (2004) 85, 1-32; which are incorporated herein by reference. In some embodiments, the pouch contents further comprise microcrystalline cellulose as described herein above.

The type of pouch may vary. Suitable pouches of the type used for the manufacture of smokeless tobacco products are available under the tradenames CatchDry, Ettan, General, Granit, Goteborgs Rape, Grovsnus White, Metropol Kaktus, Mocca Anis, Mocca Mint, Mocca Wintergreen, Kicks, Probe, Prince, Skruf and TreAnkrare. The composition may be contained in pouches and packaged, in a manner and using the types of components used for the manufacture of conventional snus types of products. The pouch provides a liquid-permeable container of a type that may be considered to be similar in character to the mesh-like type of material that is used for the construction of a tea bag. Components of the composition readily diffuse through the pouch and into the mouth of the user.

Non-limiting examples of suitable types of pouches are set forth in, for example, US Pat. Nos. 5,167,244 to Kjerstad and 8,931,493 to Sebastian et al.; as well as US Patent App. Pub. Nos. 2016/0000140 to Sebastian et al.; 2016/0073689 to Sebastian et al.; 2016/0157515 to Chapman et al.; and 2016/0192703 to Sebastian et al., each of which is incorporated herein by reference. Pouches can be provided as individual pouches, or a plurality of pouches (e.g., 2, 4, 5, 10, 12, 15, 20, 25 or 30 pouches) can be connected or linked together (e.g., in an end-to-end manner) such that a single pouch or individual portion can be readily removed for use from a one-piece strand or matrix of pouches.

The pouches of the present disclosure can be formed from a fleece material, e.g., fibrous nonwoven webs. As used herein, the term “fiber” is defined as a basic element of textiles. Fibers are often in the form of a rope- or string-like element. As used herein, the term “fiber” is intended to include fibers, filaments, continuous filaments, staple fibers, and the like. The term “multicomponent fibers” refers to fibers that comprise two or more components that are different by physical or chemical nature, including bicomponent fibers. Specifically, the term “multicomponent fibers” includes staple and continuous fibers prepared from two or more polymers present in discrete structured domains in the fiber, as opposed to blends where the domains tend to be dispersed, random or unstructured.

A "fleece material" as used herein may be formed from various types of fibers, as described in more detail herein below, capable of being formed into a traditional fleece fabrics or other traditional pouch materials. For example, fleece materials may be provided in the form of a woven or nonwoven fabric. Suitable types of fleece materials, for example, are described in U.S. Patent No. 8,931,493 to Sebastian et al.; and US Patent App. Pub. Nos. 2015/0128978 to Sebastian et al., 2016/0000140 to Sebastian et al., and US Patent App. Pub. No. 2016/0073689 to Sebastian et al.; which are all incorporated herein by reference.

The term "nonwoven" is used herein in reference to fibrous materials, webs, mats, batts, or sheets in which fibers are aligned in an undefined or random orientation. The nonwoven fibers are initially presented as unbound fibers or filaments. An important step in the manufacturing of nonwovens involves binding the various fibers or filaments together. The manner in which the fibers or filaments are bound can vary, and include thermal, mechanical and chemical techniques that are selected in part based on the desired characteristics of the final product, as discussed in more detail herein below.

In some embodiments, the pouch may be biodegradable or dissolvable. In some embodiments, after use, the entire composition, and in certain embodiments, the entirety of the pouch material originally housing the composition, can be dissolved and orally ingested by the user such that there is nothing left of the pouched product to remove from the mouth of the user. An example dissolvable pouch may be manufactured from materials, and in such a manner, such that during use by the user, the pouch undergoes a controlled dispersion or dissolution. Such pouch materials may have the form of a mesh, screen, perforated paper, permeable fabric, or the like. For example, pouch material manufactured from a mesh-like form of rice paper, or perforated rice paper, may dissolve in the mouth of the user. As a result, the pouch and composition each may undergo complete dispersion within the mouth of the user during normal conditions of use, and hence the pouch and composition both may be ingested by the user. In various embodiments, the pouch material can be dissolvable (i.e., orally ingestible) such that under conditions of normal use (i.e., upon contact with saliva in the mouth of a user), the pouch material completely dissolves. Preferably, the pouch material will dissolve after a significant amount of the soluble components of the composition within the pouch (e.g., active ingredient(s) and/or flavorant(s)) permeate through the pouch material into the mouth of the user. For example, the pouch material can be configured to dissolve at a rate such that the pouch material holds the composition together for a period of time sufficient to allow for the release of substantially all water soluble components.

As described herein, the composition within the pouch material is at least partially dissolvable. In such embodiments, the pouch material can be configured to dissolve at a rate similar to the rate at which the composition dissolves. In certain embodiments, the pouch material can be adapted to or configured to at least partially dissolve or completely dissolve in about 5 minutes or

longer, about 15 minutes or longer, about 30 minutes or longer, or about an hour or longer. In certain embodiments, the pouch material can be adapted to or configured to at least partially dissolve or completely dissolve in no less than 30 minutes, no less than 45 minutes, or no less than an hour. In some embodiments, the pouch material may be adapted to or configured to at least partially dissolve or completely dissolve in a time of about 30 seconds to about 30 minutes, about 1 minute to about 25 minutes, about 5 minutes to about 20 minutes, or about 5 minutes to about 15 minutes. Without being limited by theory, a pouched product comprising a dissolvable or biodegradable pouch material can provide environmental advantages.

In various embodiments, dissolvable pouch materials can include, but are not limited to, spun or nonwoven alginate fibers, gluten fibers, mini-perforated flat sheets derived from alginate, carrageenan, and other polymer binders, and combinations thereof. Without being limited by theory, the dissolution rate of the pouch material can be controlled by the use of cross-linking technology between alginate or pectin and calcium salts, for example. Other examples of pouch materials may be manufactured using water dispersible film forming materials (e.g., binding agents such as carboxymethylcellulose, xanthan gum, pullulan, and the like), as well as those materials in combination with materials such as ground cellulosics (e.g., fine particle size wood pulp). Preferred pouch materials, though water dispersible or dissolvable, may be designed and manufactured such that under conditions of normal use, a significant amount of the composition contents permeate through the pouch material prior to the time that the pouch undergoes loss of its physical integrity. If desired, flavoring ingredients, disintegration aids, and other desired components, may be incorporated within, or applied to, the pouch material.

In certain embodiments, the dissolvable pouch material can include fast dissolving fibers formed using an electrospinning process (*e.g.*, solution-based electrospinning) with hydrophilic polymers. *See, e.g.*, the techniques and fibers disclosed in Asawahame, Chawalinee et al., *Formation of Orally Fast Dissolving Fibers Containing Propolis by Electrospinning Technique*, Chiang Mai J. Sci. 2015; 42(2), p. 469-480, which is herein incorporated by reference in its entirety.

In some embodiments, the fibers within the fleece material may include, but are not limited to, a polymer selected from the group consisting of polyglycolic acid, polylactic acid, polyhydroxyalkanoates, polycaprolactone, polybutylene succinate, polybutylene succinate adipate, and copolymers thereof. In some embodiments, the fibers within the fleece material may be selected from the groups consisting wool, cotton, fibers made of cellulosic material, such as regenerated cellulose, cellulose acetate, cellulose triacetate, cellulose nitrate, ethyl cellulose, cellulose acetate propionate, cellulose acetate butyrate, hydroxypropyl cellulose, methyl hydroxypropyl cellulose, protein fibers, and the like. See also, the fiber types set forth in US Pat. Appl. Pub. No. 2014/0083438 to Sebastian et al., which is incorporated by reference herein. In various embodiments, the pouch material can include a polymer selected from the group consisting of polyvinylpyrrolidone, polyvinyl

alcohol, polyglycolic acid, polylactic acid, polyhydroxyalkanoates, and combinations thereof. Pouches comprising such polymers may be described as biodegradable.

Regenerated cellulose fibers can be particularly advantageous, and are typically prepared by extracting non-cellulosic compounds from wood, contacting the extracted wood with caustic soda, followed by carbon disulfide and then by sodium hydroxide, giving a viscous solution. The solution is subsequently forced through spinneret heads to create viscous threads of regenerated fibers. Example methods for the preparation of regenerated cellulose are provided in U.S. Pat. No. 4,237,274 to Leoni et al; U.S. Pat. No. 4,268,666 to Baldini et al; U.S. Pat. No. 4,252,766 to Baldini et al.; U.S. Pat. No. 4,388,256 to Ishida et al.; U.S. Pat. No. 4,535,028 to Yokogi et al.; U.S. Pat. No. 5,441,689 to Laity; U.S. Pat. No. 5,997,790 to Vos et al.; and U.S. Pat. No. 8,177,938 to Sumnicht, which are incorporated herein by reference. The manner in which the regenerated cellulose is made is not limiting, and can include, for example, both the rayon and the TENCEL processes. Various suppliers of regenerated cellulose are known, including Lenzing (Austria), Cordenka (Germany), Aditya Birla (India), and Daicel (Japan).

The form of the fibers used in the nonwoven web according to the present disclosure can vary, and include fibers having any type of cross-section, including, but not limited to, circular, rectangular, square, oval, triangular, and multilobal. In certain embodiments, the fibers can have one or more void spaces, wherein the void spaces can have, for example, circular, rectangular, square, oval, triangular, or multilobal cross-sections. As noted previously, the fibers can be selected from single-component (*i.e.*, uniform in composition throughout the fiber) or multicomponent fiber types including, but not limited to, fibers having a sheath/core structure and fibers having an islands-in-the-sea structure, as well as fibers having a side-by-side, segmented pie, segmented cross, segmented ribbon, or tipped multilobal cross-sections.

The physical parameters of the fibers present in the nonwoven web can vary. For example, the fibers used in the nonwoven web can have varying size (e.g., length, denier per filament (dpf)) and crimp characteristics. In some embodiments, fibers used in the nonwoven web can be nano fibers, sub-micron fibers, and/or micron-sized fibers. In certain embodiments, fibers of the nonwoven webs useful herein can measure about 1.5 dpf to about 2.0 dpf, or about 1.6 dpf to about 1.90 dpf. In various embodiments, each fiber can measure about 4-10 crimps per cm, or about 5-8 crimps per cm. In some embodiments, each fiber can be a continuous filament fiber. In certain embodiments, each fiber can be a staple fiber. Each fiber length can measure about 35 mm to about 60 mm, or about 38 mm to about 55 mm, for example. It can be advantageous for all fibers in the nonwoven web to have similar fiber size and crimp attributes to ensure favorable blending and orientation of the fibers in the nonwoven web.

The fibrous webs can have varying thicknesses, porosities and other parameters. The nonwoven web can be formed such that the fiber orientation and porosity of the pouched product

formed therefrom can retain the composition adapted for oral use that is enclosed within the outer water-permeable pouch, but can also allow the flavors of the composition to be enjoyed by the consumer. For example, in some embodiments, the fibrous webs can have a basis weight of about 20 gsm to about 35 gsm, or about 25 gsm to about 30 gsm. In a preferred embodiment, the fibrous web can have a basis weight of about 28 gsm. Basis weight of a fabric can be measured using ASTM D3776/D3776M-09a (2013) (Standard Test Methods for Mass Per Unit Area (Weight) of Fabric), for example. In various embodiments, the fibrous web can have a thickness of about 0.1 mm to about 0.15 mm (e.g., about 0.11 mm). The fibrous web can have an elongation of about 70% to about 80%, e.g., about 78%. In some embodiments, the fibrous web can have a peak load of about 4 lbs. to about 8 lbs., e.g., about 5.5 lbs. Elongation and breaking strength of textile fabrics can be measured using ASTM D5034-09(2013) (Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)), for example. In various embodiments, the fibrous web can have a Tensile Energy Absorption (TEA) of about 35 to about 40, e.g., about 37. In certain embodiments, the fibrous web can have a porosity of greater than about 10,000 ml/min/cm^2. TEA can be measured, for example, as the work done to break the specimen under tensile loading per lateral area of the specimen. Porosity, or air permeability of textile fabrics can be measured using ASTM D737-04(2012) (Standard Test method for Air Permeability of Textile Fabrics), for example.

In various embodiments of the pouched product described herein, the outer water-permeable pouch is made from a nonwoven web as described above. In some embodiments, a pouch is constructed of a single layer of the nonwoven web. In various embodiments, the pouch material comprises a multilayer composite made up of two or more nonwoven layers, each layer being orally ingestible. Each nonwoven layer can be formed by processes discussed below. In a multilayer structure, a first layer can be relatively hydrophilic and a second layer can be relatively hydrophobic (compared to each other). In some embodiments, an outer water-permeable pouch can comprise an outer hydrophilic layer and an inner hydrophobic layer that can be in contact with the composition adapted for oral use. As such, the hydrophobic layer can, during storage of the pouched product, retain any moisture in the composition adapted for oral use such that flavors in the composition are not lost due to moisture loss. However, capillaries in the hydrophobic layer can wick out moisture into the mouth of the user, such that flavors are released into the oral cavity when used. In this manner, the pouch material can enhance storage stability without significantly compromising the enjoyment of the product by the end user. The two layers can be formed into a multi-layer composite nonwoven material using any means known in the art, such as by attaching the two layers together using adhesive or stitching. The hydrophobicity of a textile material can be evaluated, for example, by measuring the contact angles between a drop of liquid and the surface of a textile material, as is known in the art.

In certain embodiments, the pouch material can comprise a flavor component (such as any of the flavor components noted herein), which can be applied to the nonwoven layer in any conventional manner such as by coating, printing, and the like. In some embodiments of a pouched product described herein, the flavor within an outer pouch material can differ from a flavor contained within the internal composition configured for oral use. For example, in certain embodiments, the pouch material can have a first flavor component and after the pouch material has dissolved, more moisture can reach the composition within the pouch material and a flavor component within the composition can be enhanced. In this manner, the product can be designed to provide multiple, different sensory experiences, a first sensory experience where the flavor in the outer pouch material transitions into the mouth of the user and a second sensory experience, typically occurring later in time, where the flavor of the internal composition transitions into the mouth of the user.

In some embodiments, a heat sealable binder coating or a binder material (e.g., a coating or other additive) may be added to the fibers prior to, during, or after forming the fleece material. As used herein, "heat sealable binder coatings" refers to coating materials, such as acrylic polymer compositions, applied to a substrate (e.g., a nonwoven web or fleece material) and which are capable of sealing seams of individual pouches upon heating. In some embodiments, a binder material can be added to the web fibers before or during the laying of the fibrous web (i.e., before the fibrous web is bonded to form a fleece material). In certain embodiments, a binder material can be added to the fleece material after it has been formed. In various embodiments, the binder material is in the form of a liquid coating. In certain embodiments, a binding powder can be applied to the fleece material. For example, powdered polyethylene can be used as a binder material. The liquid or powder coating can be applied, for example, between layers of fibers when cross-laying, air laying, or as an after treatment. A short exposure in an oven is sufficient to melt and fuse the binder material.

A pouched product as described herein can be packaged within any suitable inner packaging material and/or outer container. See also, for example, the various types of containers for smokeless types of products that are set forth in US Pat. Nos. 7,014,039 to Henson et al.; 7,537,110 to Kutsch et al.; 7,584,843 to Kutsch et al.; 8,397,945 to Gelardi et al., D592,956 to Thiellier; D594,154 to Patel et al.; and D625,178 to Bailey et al.; US Pat. Pub. Nos. 2008/0173317 to Robinson et al.; 2009/0014343 to Clark et al.; 2009/0014450 to Bjorkholm; 2009/0250360 to Bellamah et al.; 2009/0266837 to Gelardi et al.; 2009/0223989 to Gelardi; 2009/0230003 to Thiellier; 2010/0084424 to Gelardi; and 2010/0133140 to Bailey et al; 2010/0264157 to Bailey et al.; and 2011/0168712 to Bailey et al. which are incorporated herein by reference.

While the compositions configured for oral use as described herein have generally been described as disposed within a pouch as described, products of the present disclosure are not limited to such pouched embodiments. Accordingly, any embodiment of the disclosed composition may also be used in the absence of a pouch. For instance, a composition configured for oral use as described

herein may simply be applied directly to the oral cavity as e.g., a powder, granules, beads, tablets, pellets, or the like.

Preparation of the Composition

The composition of the disclosure may generally be prepared, for example, by dry-blending dry ingredients, such as fillers, active ingredients, salts, buffers, flavoring agents, and the like, and combining the dry mixture with any liquid ingredients, such as humectants, followed by placing the composition in a pouch.

The manner by which the various components of the composition are combined may vary. As such, the overall composition with e.g., powdered composition components may be relatively uniform in nature. The components noted above, which may be in liquid or dry solid form, can be admixed in a pretreatment step prior to mixture with any remaining components of the composition, or simply mixed together with all other liquid or dry ingredients. In certain embodiments, a liquid flavorant is combined with a porous particulate carrier, such as microcrystalline cellulose, to form a dry flavorant mixture. This dry flavorant may then be combined with the other components of the composition (e.g., dissolvable filler, active ingredient, and the like). Introduction of the flavorant in this manner may be beneficial in providing a more homogenous product, and avoiding clumping which may otherwise result from combining a liquid flavorant with other dry materials. Such clumping is undesirable, as it reduces product homogeneity, and requires further processing, such as resting time and milling. In other embodiments, the flavorant is added to the other components in dry form as e.g., a spray dried powder.

The various components of the composition may be contacted, combined, or mixed together using any mixing technique or equipment known in the art. Any mixing method that brings the composition ingredients into intimate contact can be used, such as a mixing apparatus featuring an impeller or other structure capable of agitation. Examples of mixing equipment include casing drums, conditioning cylinders or drums, liquid spray apparatus, conical-type blenders, ribbon blenders, mixers available as FKM130, FKM600, FKM1200, FKM2000 and FKM3000 from Littleford Day, Inc., Plough Share types of mixer cylinders, Hobart mixers, and the like. See also, for example, the types of methodologies set forth in US Pat. Nos. 4,148,325 to Solomon et al.; 6,510,855 to Korte et al.; and 6,834,654 to Williams, each of which is incorporated herein by reference. Manners and methods for formulating compositions will be apparent to those skilled in the art. See, for example, the types of methodologies set forth in US Pat. No. 4,148,325 to Solomon et al.; US Pat. No. 6,510,855 to Korte et al.; and US Pat. No. 6,834,654 to Williams, US Pat. Nos. 4,725,440 to Ridgway et al., and 6,077,524 to Bolder et al., each of which is incorporated herein by reference.

In some embodiments, the composition (e.g., the dry mixture) is compressed or otherwise treated prior to enclosing in a pouch. In some embodiments, the composition may be compressed

using conventional tableting techniques. Compressed pellets or tablets can be produced by compacting the dry blend, including any associated formulation components, in the form of a pellet, tablet, or the like. Example compaction devices, such as compaction presses, are available as Colton 2216 and Colton 2247 from Vector Corporation and as 1200i, 2200i, 3200, 2090, 3090 and 4090 from Fette Compacting. Devices for providing outer coating layers to compacted pelletized products are available as CompuLab 24, CompuLab 36, Accela-Cota 48 and Accela-Cota 60 from Thomas Engineering.

In some embodiments, following compression, the composition is in a compressed shape of predetermined form. Cross-sectional shapes of the composition can vary, and example cross-sectional shapes include circles, squares, ovals, rectangles, and the like. In certain embodiments, the composition is in the form of a compressed or molded pellet, wherein the pellet can have any of a variety of shapes, including traditional pill or tablet shapes. The precise shape and size will depend on the desired application.

In some embodiments, prior to or as an alternative to compressing, the dry mixture is granulated, forming a plurality of granules. Granulation is the process in which particles of the individual components, in e.g., powder form, are made to adhere to form large, homogenous, multi-particle entities called granules. Granulation is particularly suitable in embodiments where the product includes a milled non-tobacco botanical material, a botanical extract, or certain flavorants. Milled botanical materials and extracts, as well as certain flavorants, by virtue of their high moisture and/or oil content, have a tendency to stick together, forming clumps which may result in a non-homogenous product in the absence of granulation. Such clumping is also undesirable during processing, as clumping may lead to difficulty in achieving adequate flow, and is particularly undesirable in compressed (e.g., tableted) embodiments. Any suitable means for granulation may be employed. For example, granulation can be conducted in a granulator under high-shear, low-shear, fluid bed, rotor, or melt granulation.

The dry mixture may be mixed with a liquid binder or binder solution (e.g., by spraying a binder solution into the granulator) and granulated to a desired particle size, such as about 100 to about 200 microns. As would be understood in the art, the binder solution facilitates agglomeration of the dry powder granulation mixture into larger granules. The binder solution used in the granulation process can be any aqueous or alcohol-based solution containing an appropriate binder or combination of binders. In some embodiments, the binder comprises a cellulose ether as described herein above. In some embodiments, the binder comprises polyvinylpyrrolidone, or a combiniation of a cellulose ether and polyvinylpyrrolidone. In some embodiments, the binder is polyvinylpyrrolidone. The molecular weight of the polyvinylpyrrolidone may vary, and is generally specified by reference to the letter "K" followed by a number. For example, in some embodiments, the polyvinylpyrrolidone is K29/32 or

K30, meaning the polyvinylpyrrolidone has a mean molecular weight from 29,000 to 32,000, or 30,000, respectively.

The binder solution will typically have a solids content of about 3 to about 20 percent (w/w), and suitable solvents include water and ethanol. The binder solution used in the granulation process can be aqueous in nature. In some embodiments, the binder solution includes at least one active ingredient, at least one flavorant, or a combination thereof. The binder solution, the dry mixture, or both, can contain other additives, including any of the additives discussed herein, such as salts, buffers, non-tobacco botanical material, sweeteners, processing aids, and the like. Such additives may be added before or after granulation.

In some embodiments, the compositions of the disclosure can be prepared in beaded form using various methods, including extrusion and spheronization, prilling, spray granulation, briquetting, and/or roller compaction. Typically, the mixture of components (e.g., dissolvable filler, active ingredient and/or flavorant, and humectant) is granulated as described herein above to form an agglomerate. Without wishing to be bound by theory, it is believed that employing a humectant such as glycerin in an amount up to about 20% by weight of the composition is advantageous in both providing the desired properties to the composition and in facilitating processing. Typically, the agglomerate is then extruded. The extrusion can be carried out using extruders such as screw, sieve, basket, roll, and ram-type extruders, extruding the agglomerate through suitably sized pierced screens. Any suitable extrudate shape may be used. In some embodiments, the agglomerate is extruded into rods. The extrudate is then processed in a spheronizer (e.g., such as spheronizers (marumerizers) available from Caleva Process Solutions Ltd. or LCI Corporation) at a suitable rotation speed (e.g., 1200 RPM) for a suitable time (e.g., 10 minutes). For example, spheronization can be carried out using a spinning friction plate that effects rounding of extrudate particles. Following spheronization, the composiiton is obtained in the form of variously sized beads. the variously-sized beads can be processed through a series of screens to provide the desired size range, such as from about 700 to about 2000 μm in diameter).

The composition in the form of beads, or compressed pellets or tablets, can include an optional outer coating, which can help to improve storage stability of the composition as well as improve the packaging process by reducing friability and dusting. Accordingly, in some embodiments, the method further comprises coating the composition in beaded or compressed form. The coating typically comprises a film-forming polymer, such as a cellulosic material, an optional plasticizer, and optional flavorants, colorants, salts, sweeteners or other additives of the types set forth herein. The coating compositions are usually aqueous in nature and can be applied using any pellet or tablet coating technique known in the art, such as pan coating. Example film-forming polymers include cellulosic materials such as methylcellulose, hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), hydroxyethyl cellulose, and carboxymethylcellulose (CMC). Example

plasticizers include aqueous solutions or emulsions of glyceryl monostearate and triethyl citrate. Additional potential coatings include food grade shellac, waxes such as carnuaba wax, paraffin wax, and beeswax, oils such as palm oil and sunflower oil, and combinations thereof. In some embodiments, the composition in the form of beads, or compressed pellets or tablets, can include a release modifying coating as described herein above.

Method of Making a Pouched Product

Various manufacturing apparati and methods can be used to create a pouched product described herein. For example, US Publication No. 2012/0055493 to Novak, III et al., previously incorporated by reference in its entirety, relates to an apparatus and process for providing pouch material formed into a tube for use in the manufacture of smokeless tobacco products. Similar apparatuses that incorporate equipment for supplying a continuous supply of a pouch material (e.g., a pouch processing unit adapted to supply a pouch material to a continuous tube forming unit for forming a continuous tubular member from the pouch material) can be used to create a pouched product described herein. Representative equipment for forming such a continuous tube of pouch material is disclosed, for example, in U.S. Patent Application Publication No. US 2010/0101588 to Boldrini et al., which is incorporated herein by reference in its entirety. The apparatus further includes equipment for supplying pouched material to the continuous tubular member such that, when the continuous tubular member is subdivided and sealed into discrete pouch portions, each pouch portion includes a charge of a composition adapted for oral use. Representative equipment for supplying the filler material is disclosed, for example, in U.S. Patent Application Publication No. US 2010/0018539 to Brinkley, which is incorporated herein by reference in its entirety. In some instances, the apparatus may include a subdividing unit for subdividing the continuous tubular member into individual pouch portions and, once subdivided into the individual pouch portions, may also include a sealing unit for sealing at least one of the ends of each pouch portion. In other instances, the continuous tubular member may be sealed into individual pouch portions with a sealing unit and then, once the individual pouch portions are sealed, the continuous tubular member may be subdivided into discrete individual pouch portions by a subdividing unit subdividing the continuous tubular member between the sealed ends of serially-disposed pouch portions. Still in other instances, sealing (closing) of the individual pouch portions of the continuous tubular member may occur substantially concurrently with the subdivision thereof, using a closing and dividing unit. It is noted that in certain embodiments of the present disclosure wherein a low melting point binder material is used, the temperature required for sealing the seams of the pouched product can be less than the temperature required in conventional processes associated with conventional binder materials.

In some embodiments, the composition is introduced into the pouch material in the form of a particulate material (e.g., as a dry powder). In dry powder embodiments, it has been found that

pouching of dry powder compositions was associated with disadvantages, such as airborne dust, melting of powder on the heat sealing knife, and scorch marks on the pouches. It has been found according to the present disclosure that introducing a humectant such as propylene glycol in an amount up to about 5% by weight, based on the total weight of the composition, may reduce or prevent dusting and issues associated with such dusting. Further, it has been found according to the present disclosure that introducing the composition in the form of beads or compressed pellets or tablets also avoids such issues. Accordingly, in some embodiments, the composition is introduced into the pouch material in the form of beads. In some embodiments, the composition is introduced into the pouch material in the form of one or more compressed tablets or pellets.

Many modifications and other embodiments of the invention will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing description. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

EXAMPLES

Aspects of the present invention are more fully illustrated by the following examples, which are set forth to illustrate certain aspects of the present invention and are not to be construed as limiting thereof.

Example 1. Pouched Product-Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared from the formulation provided in Table 2. The actual ingredients and percentages can be varied depending on the desired properties of the final product.

The liquid flavor was absorbed into the microcrystalline cellulose and mixed until uniform. This absorbed flavorant was then added into the other components. The materials were mixed, then extruded through a 1.5 mm die. The extruded material was spheronized in a marumerizer, and the formed beads classified to give a bead mixture with a size range from about 25-10 mesh, such as about 14 mesh size. The beaded composition (about 500 mg) was enclosed in a fleece pouch comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness, indicating product completion.

Table 2. Exemplary bead formulation

Dry Ingredients	Weight%
isomalt powder	67-74
glycerin	18-20

Dry Ingredients	Weight%
microcrystalline cellulose	0.95-1.05
nicotine polacrilex (20% nicotine)	4-6
sweetener	0.15-0.25
sodium benzoate	2.7-4.1
flavorant	0.8-1.2

Example 2. Pouched Product-Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared using the beaded material of Example 1 (500 mg) and a fleece comprising Lyocell, PHA, and PLA.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness indicating product completion.

Example 3. Pouched Product-Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 3. The materials were mixed as in Example 1, then extruded through a 1.5 mm die. The extruded material was spheronized in a marumerizer, and the formed beads classified to give a bead mixture with a size range from about 25-10 mesh, such as about 14 mesh size. The beaded composition (about 500 mg) was enclosed in a fleece pouch comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness, indicating product completion.

Table 3. Exemplary bead formulation

Dry Ingredients	Weight%
isomalt powder	70-77.4
glycerin	18-20
microcrystalline cellulose	1.05-1.15
nicotine polacrilex (20% nicotine)	2-3
sweetener	0.15-0.25
sodium benzoate	1.4-2.0
flavorant	0.8-1.2

Example 4. Pouched Product-Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 4. The materials were mixed as in Example 1, then extruded

through a 1.5 mm die. The extruded material was spheronized in a marumerizer, and the formed beads classified to give a bead mixture with a size range from about 25-10 mesh, such as about 14 mesh size. The beaded composition (about 500 mg) was enclosed in a fleece pouch comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness, indicating product completion.

Table 4. Exemplary bead formulation

Dry Ingredients	Weight%
isomalt powder	71-78.4
glycerin	16.6-18.4
microcrystalline cellulose	0.95-1.05
nicotine bitartrate	2.5-3.5
sweetener	0.25-0.35
sodium carbonate	2.5-3.5
flavorant	0.4-0.6

Example 5. Pouched Product-Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 5. The materials were mixed as in Example 1, then extruded through a 1.5 mm die. The extruded material was spheronized in a marumerizer, and the formed beads classified to give a bead mixture with a size range from about 25-10 mesh, such as about 14 mesh size. The beaded composition (about 500 mg) was enclosed in a fleece pouch comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness, indicating product completion.

Table 5. Exemplary bead formulation

Dry Ingredients	Weight%
isomalt powder	70-77.4
glycerin	17.9-19.7
microcrystalline cellulose	1.05-1.15
nicotine bitartrate	2-3
sweetener	0.15-0.25
sodium benzoate	1.4-2.0
flavorant	0.8-1.2
Sodium stearyl fumarate	0.8-1.2

Example 6. Pouched Product-Coated Beaded Composition

A pouched product according to an embodiment of the present disclosure was prepared using the beaded material of Example 5. Melted palm oil (4.8% by weight) was added to the beaded material and hand mixed to coat the beaded material. The coated material was used to form a pouched oral product with about 500 mg beaded material and a fleece comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give a gradual release of nicotine and dissolution of the internal content. After dissolution of the contents, the pouch was reduced in thickness indicating product completion. Pouches made with coated material were found to have delayed nicotine release relative to pouched materials made with the beads of Example 5.

Example 7. Pouched Product-Powder Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 6. The materials were mixed to form the composition. About 500 mg of the composition was enclosed in a fleece pouch to form the pouched product. In use, the materials inside the pouch dissolved, leaving the fleece.

Table 6. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	37.5-56.5
maltodextrin	37.5-56.5
nicotine bitartrate	2-3
sweetener	0.2-0.4
sodium carbonate	2-4
flavorant	0.6-1.0

Example 8. Pouched Product-Powder Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 7. The materials were mixed to form the composition. About 500 mg of the composition was enclosed in a fleece pouch to form the pouched product. In use, the materials inside the pouch dissolved, leaving the fleece.

Table 7. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	30-44.5
maltodextrin	30-44.5
lactose	16-24
nicotine bitartrate	2-3
sweetener	0.2-0.4
sodium carbonate	2-4
flavorant	0.6-1.0

Example 9. Pouched Product-Powder Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 8. The materials were mixed to form the composition. About 500 mg of the composition was enclosed in a fleece pouch to form the pouched product. In use the materials inside the pouch dissolved, leaving the fleece.

Table 8. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	33-50
maltodextrin	37.5-56.5
microcrystalline cellulose	4-6
nicotine bitartrate	2-3
sweetener	0.2-0.4
sodium carbonate	2-4
flavorant	0.4-0.6

Example 10. Pouched Product-Powder Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 9. The materials were mixed to form the composition. About 500 mg of the composition was enclosed in a fleece pouch to form the pouched product. In use the materials inside the pouch dissolved, leaving the fleece.

Table 9. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	33-50
maltodextrin	33-50
Microcrystalline cellulose	8-12
nicotine bitartrate	2-3
sweetener	0.2-0.4
sodium carbonate	2-4
flavorant	0.4-0.6

Example 11. Pouched Product-Powder Composition

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 10. The materials were mixed to form the composition. About 500 mg of the composition was enclosed in a fleece pouch to form the pouched product. In use the materials inside the pouch dissolved, leaving the fleece.

Table 10. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	22-33
maltodextrin	21-32

Dry Ingredients	Weight%
microcrystalline cellulose	32-48
nicotine bitartrate	2-3
sweetener	0.2-0.4
sodium carbonate	2-4
flavorant	0.4-0.6

Example 12. Pouched Product-Beaded Composition with Elastomeric Component

A pouched product according to an embodiment of the present disclosure was prepared using the formulation provided in Table 11. The materials were mixed, then extruded through a 1.5 mm die. The extruded material was spheronized in a marumerizer, and the formed beads classified to give a bead mixture with a size range from about 25-10 mesh, such as about 14 mesh size. The beaded composition (about 400 mg) was enclosed in a fleece pouch comprising viscose and viscose polyester blend with acrylate binder.

The pouched oral product was found to give release of nicotine and partial dissolution (approximately 50% by weight or more) of the internal content. The pouch exhibited a chewing gum-like character.

Table 11. Exemplary powder formulation

Dry Ingredients	Weight%
isomalt powder	46-50
Gum arabic	19-21
glycerine	18-20
microcrystalline cellulose	0.95-1.05
nicotinepolacrilex (20% nicotine)	4-6
sweetener	0.2-0.4
sodium benzoate	3-4
sodium carbonate	0.1-0.3
flavorant	0.8-1.2
sodium chloride	0.1-0.6

CLAIMS

What is claimed is:

1. A pouched product comprising an outer water-permeable pouch defining a cavity and a composition configured for oral use situated within the cavity, wherein the composition is at least partially dissolvable, the composition comprising:

one or more dissolvable fillers in an amount of at least about 45% by weight, based on the total weight of the composition;

a humectant in an amount up to about 25% by weight, based on the total weight of the composition; and

at least one active ingredient, at least one flavorant, or both at least one active ingredient and at least one flavorant.

2. The pouched product of claim 1, wherein the composition is at least about 50% orally dissolvable on a weight basis.

3. The pouched product of claim 1 or 2, wherein from about 95% to about 100% of the composition by weight is orally dissolvable.

4. The pouched product of any one of claims 1-3, wherein the one or more dissolvable fillers is selected from the group consisting sugars, sugar alcohols, soluble starches, soluble fibers, and combinations thereof.

5. The pouched product of any one of claims 1-4, wherein the one or more dissolvable fillers comprise a sugar alcohol.

6. The pouched product of claim 5, wherein the sugar alcohol is isomalt.

7. The pouched product of claim 5 or 6, wherein the one or more dissolvable fillers further comprise maltodextrin.

8. The pouched product of any one of claims 1-7, wherein the humectant is present in an amount from about 15 about 20% by weight, based on the total weight of the composition.

9. The pouched product of any one of claims 1-8, wherein the humectant is glycerin, propylene glycol, or a mixture thereof.

10. The pouched product of any one of claims 1-9, wherein the composition further comprises at least one sweetener.

11. The pouched product of claim 1, wherein the composition is in particulate form, granulated form, or in the form of one or more pellets or tablets.

12. The pouched product of claim 11, wherein the one or more dissolvable fillers comprise a sugar alcohol and maltodextrin, and optionally, wherein the composition further comprises microcrystalline cellulose in an amount up to about 40% by weight of the composition.

13. The pouched product of claim 1, wherein the composition is in the form of beads, the composition comprising a sugar alcohol in an amount from about 67% to about 78% by weight, based on the total weight of the composition, and glycerin in an amount from about 16% to about 20% by weight, based on the total weight of the composition.

14. The pouched product of claim 13, wherein the sugar alcohol is isomalt.

15. The pouched product of claim 13 or 14, wherein the composition further comprises microcrystalline cellulose in an amount of up to about 5% by weight of the composition.

16. The pouched product of any one of claims 13-15, wherein at least a portion of the beads are coated with a release modifying agent selected from the group consisting of lipids, waxes, cellulose derivatives, binders, and combinations thereof.

17. The pouched product of any one of claims 13-16, wherein the pouched product comprises a mixture of beads having different dissolution rates.

18. The pouched product of any one of claims 13-17, further comprising microcrystalline cellulose in the form of a physical mixture with the beads.

19. The pouched product of any one of claims 1-18, wherein the at least one active ingredient is selected from the group consisting of botanical materials, stimulants, amino acids, vitamins, antioxidants, cannabinoids, cannabimimetics, terpenes, pharmaceutical agents, and combinations thereof.

20. The pouched product of any one of claims 1-19, wherein the at least one active ingredient comprises a nicotine component.

21. The pouched product of claim 20, wherein the nicotine component comprises resin-bound nicotine.

22. The pouched product of any one of claims 1-21, wherein the composition further comprises one or more organic acids, an alkali metal salt of the one or more organic acids, or both.

23. The pouched product of claim 22, wherein the one or more organic acids or alkali metal salt thereof is present in the composition in an amount by weight of from about 0.1 to about 10%, or from about 0.1 to about 0.5%, based on the total weight of the composition.

24. The pouched product of claim 22 or 23, wherein the one or more organic acids is citric acid, malic acid, tartaric acid, octanoic acid, benzoic acid, a toluic acid, salicylic acid, or a combination thereof.

25. The pouched product of any one of claims 22-24, wherein at least a portion of the organic acid, the alkali metal salt of the organic acid, or both are associated with at least a portion of the nicotine component in the form of an ion pair.

26. The pouched product of any one of claims 1-25, wherein the outer water-permeable pouch is biodegradable.

27. The pouched product of any one of claims 1-26, wherein the outer water-permeable pouch is dissolvable.

FIG. 1

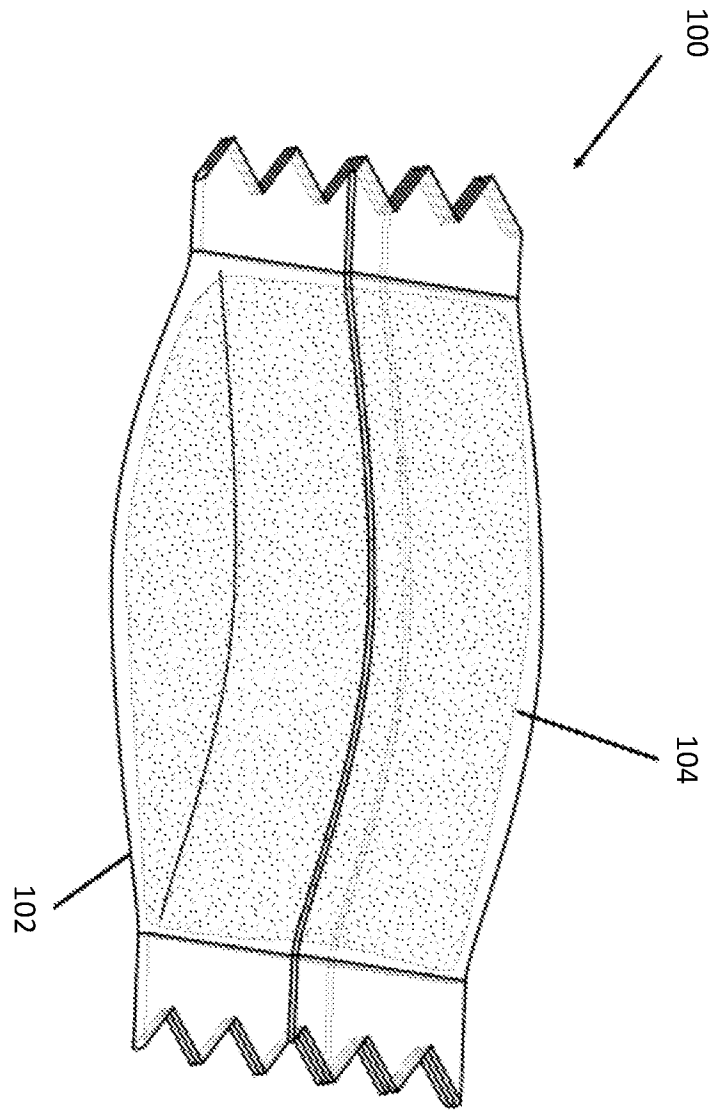


FIG. 2

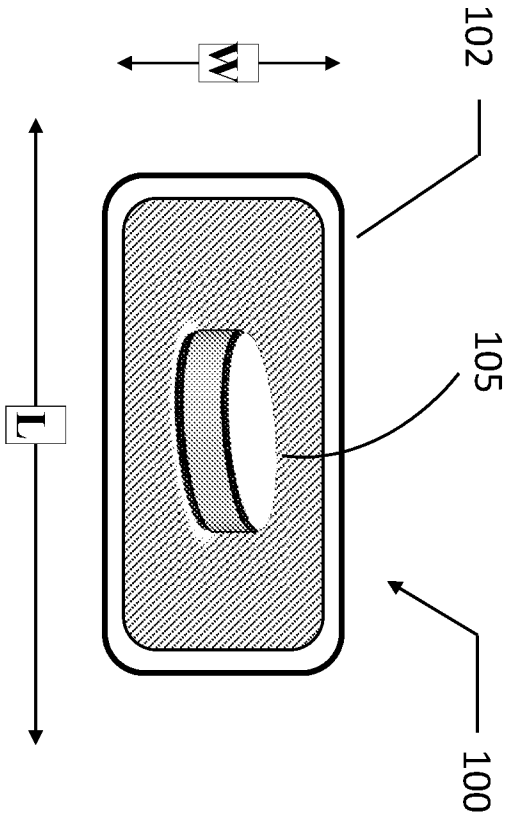
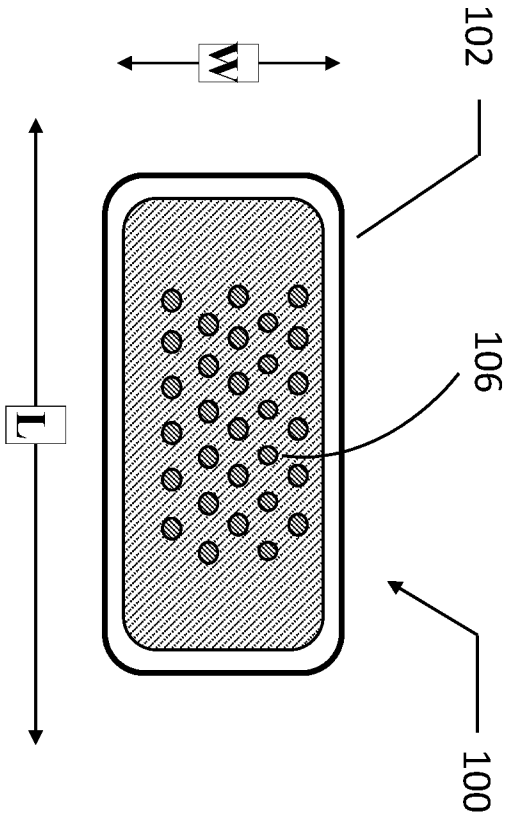


FIG. 3



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2022/055555

A. CLASSIFICATION OF SUBJECT MATTER
INV. A24B13/00 A24B15/28 A24B15/30
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A24B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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Y	paragraph [0005]	16
A	paragraph [0008]	17,21,25
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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

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"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
1 September 2022	16/09/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Dimoula, Kerasina

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