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(73) Patenthaver: **Nicoventures Trading Limited, Globe House , 1 Water Street, London, Greater London WC2R 3LA, Storbritannien**

(72) Opfinder: **BEESON, Dwayne William, c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien**
HUNT, Philip Richard, c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
HUTCHENS, Ronald K., c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
KELLER, Christopher, c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
POOLE, Thomas H., c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
ST. CHARLES, Frank Kelley, c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
GESSESSE, Andinet Amare, Jr., c/o Nicoventures Trading Limited Globe House, 1 , Water Street, London, Greater London WC2R 3LA, Storbritannien
HOLTON, Darrell Eugene, Jr., 5331 Sterling Forest Drive, Clemmons, North Carolina 27012, USA

(74) Fuldmægtig i Danmark: **NORDIC PATENT SERVICE A/S, Bredgade 30, 1260 København K, Danmark**

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DESCRIPTION

Description

FIELD OF THE DISCLOSURE

[0001] The present disclosure relates to flavored products 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

[0002] 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..

[0003] 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.. US2013206153 discloses a whitened tobacco composition; EP3087852 discloses an oral pouched product having a rectangular shape; WO2018197454 and WO2019115778 disclose a flavoured moist oral pouched nicotine product comprising triglyceride; US2010300464 discloses moist botanical pouch processing and moist oral botanical pouch products; US2010218779 discloses controlled flavour release tobacco pouch products and methods of making; WO2009015142 discloses smokeless tobacco compositions and methods of treating tobacco for use therein; US2009025739 and US2007186941 disclose smokeless tobacco compositions.

[0004] All-white snus portions are growing in popularity, and offer a discrete and aesthetically pleasing alternative to traditional snus. Such modern "white" pouched products may include a bleached tobacco or may be tobacco-free. Products of this type may suffer from certain drawbacks, such as poor product stability that could lead to discoloration of the product and/or undesirable organoleptic characteristics.

BRIEF SUMMARY

[0005] The present disclosure generally provides compositions and products configured for oral use. The products may be configured to impart a taste when used orally and, additionally or alternatively, may deliver active ingredients to a consumer, such as nicotine. The products and methods of the present disclosure in particular may be adapted or configured to provide one or more materials to a consumer at a controlled release rate, such as a sustained release.

[0006] 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 DRAWING

[0007] Having thus described aspects of the disclosure in the foregoing general terms,

reference will now be made to the accompanying drawing, which is not necessarily drawn to scale. The drawing is exemplary only, and should not be construed as limiting the disclosure.

[0008] The Figure is a perspective view of a pouched product according to an example embodiment of the present disclosure including a pouch or fleece at least partially filled with a composition for oral use.

DETAILED DESCRIPTION

[0009] The present disclosure provides compositions and products formed therefrom, the compositions and products particularly being configured for oral use. The compositions and products may incorporate one or more active agents and one or more filler components. The compositions and products likewise can provide a desired sensory property in the mouth of a consumer, such as providing a feeling of moistness, and the compositions and products thus can include at least a minimum content of water or other moistening agent.

[0010] 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. 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 mixture including water. Unless otherwise indicated, reference to "weight percent" of a mixture reflects the total wet weight of the mixture (i.e., including water).

[0011] The present disclosure provides a composition that may be included in products. More particularly, in some embodiments, the disclosure provides for oral compositions including at least one active agent, at least one filler component, and water. The water preferably can be present in an amount sufficient such that the oral composition has a total moisture content of about 15% by weight or greater based on the total weight of the oral composition. As described, the compositions may be provided in a variety of forms and, as further described herein, specifically, may be provided in a substantially solid form, such as a collection of particles, fibers, or the like. Accordingly, a product may include the composition itself, or the composition positioned within a unitizing structure, such as a pouch, a fleece, or the like. In some embodiments, the products as described herein comprise a mixture of components, typically including at least one carrier and/or filler and at least one flavoring agent and/or active ingredient. In some embodiments, the composition further comprises one or more salts, one or more sweeteners, one or more binding agents, one or more humectants, one or more gums, an organic acid, a tobacco material, a tobacco-derived material, or a combination thereof. 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.

Carrier/Filler Component

[0012] Compositions as described herein include at least one component that may be characterized as being a carrier component and/or a filler component. In some embodiments, the compositions may include both of a carrier and a filler, and various materials may fulfill the function of both a carrier and a filler. A carrier component according to the present disclosure preferably may be adapted to or configured to retain at least a flavor component and/or an active agent as described herein and may, in some embodiments, retain substantially all of the further components of the composition. A filler component 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 filler components are porous particulate materials. In some embodiments, the present compositions may comprise a carrier. In further embodiments, the present compositions may comprise a carrier and a filler.

[0013] The carrier component and/or a filler component is cellulose-based. For example, suitable particulate components 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 particulate carrier and/or filler components include maltodextrin, dextrose, calcium carbonate, calcium phosphate, lactose, mannitol, xylitol, and sorbitol. Combinations of materials can also be used.

[0014] "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 mixture based on the ability of the starch material to impart a specific organoleptic property to composition. 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 "genetically modified" starches. Other starches are obtained and subsequently modified by chemical, enzymatic, or physical means. 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, acetylation, hydroxypropylation, and/or partial hydrolysis. Enzymatic treatment includes subjecting native starches to enzyme isolates or concentrates, microbial enzymes, and/or enzymes native to plant materials, e.g., amylase present in corn kernels to modify corn starch. 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.

[0015] In some embodiments, a carrier component and/or a filler component may be a cellulose material or cellulose derivative. One particularly suitable material for use in the products described herein 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 one embodiment, a composition as described herein may comprise MCC as a particulate filler component and/or as a carrier component. The quantity of MCC present in the compositions as described herein may vary according to the desired properties. In some embodiments, a cellulose derivative or a combination of such derivatives in particular may be used in combination with a different carrier component, and this particularly can include cellulose derivatives, such as 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 one embodiment, the cellulose derivative is HPC.

[0016] The total amount of carrier component(s) and filler component(s) present in the composition can vary, but is typically up to about 75 percent of the composition by weight, based on the total weight of the composition. A typical range of total carrier and/or filler component within the composition can be from about 10 to about 75 percent by total weight of the composition, for example, from about 10, about 15, about 20, about 25, or about 30, to

about 35, about 40, about 45, or about 50 weight percent (e.g., about 20 to about 50 weight percent or about 25 to about 45 weight percent). In certain embodiments, the total amount of carrier/filler component is at least about 10 percent by weight, such as at least about 20 percent, or at least about 25 percent, or at least about 30 percent, or at least about 35 percent, or at least about 40 percent, based on the total weight of the composition.

[0017] In one or more embodiments, a carrier component may be adapted to or configured to substantially surround or envelop further components of the composition. For example, the carrier may be configured as a packet, a pouch, a fleece, or the like, and such structures are further described herein. The term "fleece" may particularly be used herein as a common term for such structures and should not be viewed as limiting the nature of the structure.

[0018] A suitable fleece, for example, may be formed of a plurality of fibers. The term "fiber" as used herein includes both fibers of finite length, such as conventional staple fibers and nanofibers, as well as substantially continuous structures, such as continuous filaments, unless otherwise indicated. The fibers can have a substantially round or circular cross section or non-circular cross sections (for example, oval, rectangular, multi-lobed, and the like). The fibers can be provided in a variety of configurations, and the fibers particularly can include multicomponent fibers.

[0019] In some embodiments, the fleece can be in the form of a non-woven material. 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. In some embodiments, the plurality of fibers used in forming a fleece may include heat sealable and/or meltable binder fibers. Further aspects of a suitable pouch or fleece are further described below.

Active Ingredients

[0020] In some embodiments the present compositions and products may comprise at least one active ingredient or agent. As used herein, an "active ingredient" refers to one or more substances belonging to any of the following categories: API (active pharmaceutical ingredient), 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. For example, the compositions and products may include a single active ingredient or a plurality of active ingredients. If desired, at least one active ingredient may be retained on at least a portion of the at least one filler component, and one or more active ingredients may be otherwise retained in the compositions and/or products, such as being bound to a further filler or being present in a unitary form (e.g., pelletized active ingredients).

[0021] Non-limiting examples of active ingredients include those falling in the categories of botanical ingredients, stimulants, amino acids, nicotine components, and/or pharmaceutical, nutraceutical, and medicinal ingredients (e.g., vitamins, such as A, B3, B6, B12, and C, and/or cannabinoids, such as tetrahydrocannabinol (THC) and cannabidiol (CBD)). 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.

[0022] In certain embodiments, the active ingredient is selected from the group consisting of caffeine, taurine, GABA, theanine, vitamin C, B vitamins (e.g., vitamin B6 or B12), lemon balm extract, tryptophan, ginseng, citicoline, sunflower lecithin, and combinations thereof. For example, the active ingredient can include a combination of caffeine, theanine, and optionally ginseng. In another embodiment, the active ingredient includes a combination of theanine, gamma-amino butyric acid (GABA), and lemon balm extract. In a further embodiment, the active ingredient includes theanine, theanine and tryptophan, or theanine and one or more B vitamins (e.g., vitamin B6 or B12). In a still further embodiment, the active ingredient includes a combination of caffeine, taurine, and vitamin C.

[0023] 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

[0024] 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). In some embodiments, the compositions as disclosed herein can be characterized as free of any tobacco material (e.g., any embodiment as disclosed herein may be completely or substantially free of any tobacco material). By "substantially free" is meant that no tobacco material has been intentionally added. For example, certain embodiments can be characterized as having less than 0.001% by weight of tobacco, or less than 0.0001%, or even 0% by weight of tobacco.

[0025] 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.

[0026] 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, cannabis, 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.*

[0027] In some embodiments, the active ingredient comprises lemon balm. Lemon balm (*Melissa officinalis*) is a mildly lemon-scented herb from the same family as mint (*Lamiaceae*). The herb is native to Europe, North Africa, and West Asia. The tea of lemon balm, as well as the essential oil and the extract, are used in traditional and alternative medicine. In some embodiments, the active ingredient comprises lemon balm extract. In some embodiments, the lemon balm extract is present in an amount of from about 1 to about 4% by weight, based on the total weight of the composition.

[0028] In some embodiments, the active ingredient comprises ginseng. Ginseng is the root of plants of the genus *Panax,* which are characterized by the presence of unique steroid saponin phytochemicals (ginsenosides) and gintonin. Ginseng finds use as a dietary supplement in energy drinks or herbal teas, and in traditional medicine. Cultivated species include Korean ginseng (*P. ginseng*), South China ginseng (*P. notoginseng*), and American ginseng (*P. quinquefolius*). American ginseng and Korean ginseng vary in the type and quantity of various ginsenosides present. In some embodiments, the ginseng is American ginseng or Korean ginseng. In specific embodiments, the active ingredient comprises Korean ginseng. In some embodiments, ginseng is present in an amount of from about 0.4 to about 0.6% by weight, based on the total weight of the composition.

Stimulants

[0029] 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.

[0030] 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. In some embodiments, the composition comprises caffeine in an amount of from about 1.5 to about 6% by weight, based on the total weight of the composition;

Amino acids

[0031] 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. In some embodiments, the active ingredient comprises theanine. In some embodiments, the active ingredient comprises GABA. In some embodiments, the active ingredient comprises a combination of theanine and GABA. In some embodiments, the active ingredient is a combination of theanine, GABA, and lemon balm. In some embodiments, the active ingredient is a combination of caffeine, theanine, and ginseng. In some embodiments, the active ingredient comprises taurine. In some embodiments, the active ingredient is a combination of caffeine and taurine.

[0032] When present, an amino acid or combination of amino acids (e.g., theanine, GABA, 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.

Vitamins

[0033] 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.

[0034] 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 6% 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%, about 1%, about 2%, about 3%, about 4%, about 5% , or about 6% by weight, based on the total weight of the composition.

Antioxidants

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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

[0039] In certain embodiments, the active ingredient comprises a nicotine component. 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. 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.

[0040] 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). 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.

[0041] 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.. 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.

[0042] 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.

[0043] In some embodiments, the products or compositions of the disclosure can be characterized as 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.

[0044] In some embodiments, the active ingredient comprises a nicotine component (e.g., any product or composition of the disclosure, in addition to comprising any active ingredient or combination of active ingredients as disclosed herein, may further comprise a nicotine component).

[0045] In one or more embodiments, an amount of a nicotine component that may be present in the compositions and products can be at least partially related to the total moisture content of the compositions and products. Accordingly, it can be desirable for the nicotine component content and the total moisture content to be within a desired ratio. For example, in some embodiments, a weight to weight ratio of total nicotine content to total moisture content can be substantially low and thus may be in the range of about 0.01 to about 0.2, about 0.02 to about 0.1, or about 0.03 to about 0.08.

[0046] In some embodiments, it can be desirable to provide compositions and products having a relatively high nicotine content. For example, in such embodiments, the nicotine component may be present in an amount of greater than 2%, greater than 2.5%, greater than 3%, or greater than 3.5% by weight based on the total weight of the composition or product. In another embodiment, the nicotine component may be present in an amount of about 2% to about 10%, about 3% to about 10%, or about 4% to about 8% by weight based on the total weight of the oral composition. Where nicotine is present in a relatively high content, it can likewise be desirable for the total moisture content of the compositions and products to be relatively high. The total moisture content is in the range of 20% to 45% by weight based on

the total weight of the composition or product. In addition to the foregoing, it may be desirable in some embodiments for the present compositions and products to be substantially or completely free of any tobacco material. This may be particularly the case in compositions having a relatively high nicotine content and/or high water content; however, the express absence of any tobacco may be applied to other embodiments of the present disclosure. As further described herein, it can be desirable in some embodiments for the compositions or products to exhibit a defined pH, which may be achieved through the use of suitable buffers or overall combination of materials in light of their natural acidity level (high or low). In some embodiments, such as where a high nicotine, high moisture content product is desired, it may be useful to control the overall composition (include the addition or exclusion of any buffers) to provide a pH that is greater than 7, greater than 7.5, greater than 8, or greater than 8.5. In particular, pH for such compositions may be in the range of about 7.5 to about 11, 7.5 to about 10, or about 8 to about 9.5. In certain embodiments, it thus may be useful to provide compositions or products having a relatively high nicotine content, a relatively high water content, expressly exclude tobacco, and optionally have a pH within the above-noted ranges.

[0047] In some embodiments, it can be useful to provide compositions and products having a relatively low nicotine content. For example, in such embodiments, the nicotine component may be present in an amount of less than 1%, less than 0.8%, less than 0.7%, or less than 0.5% by weight based on the total weight of the composition or product. In another embodiment, the nicotine component may be present in an amount of about 0.01% to about 0.9%, about 0.05% to about 0.8%, about 0.1% to about 0.7%, or about 0.2% to about 0.5% by weight based on the total weight of the composition or product. Where nicotine is present in a relatively low content, it can be desirable for the total moisture content of the compositions and products to be within a defined range. For example, a suitable total moisture content may be in the range of about 10% to about 40%, about 15% to about 30%, or about 20% to about 30% by weight based on the total weight of the composition or product.

Cannabinoids

[0048] In some embodiments, the active ingredient comprises one or more cannabinoids. As used herein, the term "cannabinoid" refers to a class of diverse chemical compounds that acts on cannabinoid receptors, also known as the endocannabinoid system, in cells that alter neurotransmitter release in the brain. Ligands for these receptor proteins include the endocannabinoids produced naturally in the body by animals; phytocannabinoids, found in cannabis; and synthetic cannabinoids, manufactured artificially. Cannabinoids found in cannabis include, without limitation: cannabigerol (CBG), cannabichromene (CBC), cannabidiol (CBD), tetrahydrocannabinol (THC), cannabinol (CBN), 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), tetrahydrocannabinolic acid (THCA), and tetrahydrocannabivarinic acid (THCV A). In certain embodiments, the cannabinoid is selected from tetrahydrocannabinol

(THC), the primary psychoactive compound in cannabis, and cannabidiol (CBD) another major constituent of the plant, but which is devoid of psychoactivity. All of the above compounds can be used in the form of an isolate from plant material or synthetically derived.

[0049] Alternatively, the active ingredient can be 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.

[0050] When present, a cannabinoid (e.g., CBD) or cannabimimetic is typically in a concentration of at least about 0.1% by weight of the composition, such as in a range from about 0.1% to about 30%, such as, e.g., from 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 15%, about 20%, or about 30% by weight, based on the total weight of the composition.

Terpenes

[0051] 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, isomenthone, piperitone, myrcene, beta-bourbonene, and germacrene, which may be used singly or in combination.

Pharmaceutical ingredients

[0052] In some embodiments, the active ingredient comprises an active pharmaceutical ingredient (API). The API 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, phospholipids, inorganic compounds (e.g., magnesium, selenium, zinc, nitrate), neurotransmitters or precursors thereof (e.g., serotonin, 5-hydroxytryptophan, oxitriptan, acetylcholine, dopamine, melatonin), and nucleic acid sequences, having therapeutic, prophylactic, or diagnostic activity. Non-limiting examples of APIs include analgesics and antipyretics (e.g., acetylsalicylic acid, acetaminophen, 3-(4-isobutylphenyl)propanoic acid), phosphatidylserine, myoinositol, docosahexaenoic acid (DHA, Omega-3), arachidonic acid (AA, Omega-6), S-adenosylmethionine (SAM), beta-hydroxy-beta-

methylbutyrate (HMB), citicoline (cytidine-5'-diphosphate-choline), and cotinine. In some embodiments, the active ingredient comprises ciricoline. In some embodiments, the active ingredient is a combination of citicoline, caffeine, theanine, and ginseng. In some embodiments, the active ingredient comprises sunflower lecithin. In some embodiments, the active ingredient is a combination of sunflower lecithin, caffeine, theanine, and ginseng.

[0053] The amount of API may vary. For example, when present, an API is typically at a concentration of from about 0.001% w/w to about 10% 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%, 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%, about 0.9%, or about 1%, to about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, or about 10% by weight, based on the total weight of the composition.

[0054] In some embodiments, the composition is substantially free of any API. By "substantially free of any API" means that the composition does not contain, and specifically excludes, the presence of any API as defined herein, such as any Food and Drug Administration (FDA) approved therapeutic agent intended to treat any medical condition.

Flavoring Agents

[0055] In some embodiments, a releasable material may be one or more 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. In some embodiments, the releasable material may include a single flavoring agent or a plurality of flavoring agents. If desired, one or more flavoring agents may be retained on a portion of a carrier or filler, and one or more flavoring agents may be otherwise retained in the compositions and/or products, such as being bound to a further carrier or filler.

[0056] Non-limiting examples of flavoring agents that may be used as a releasable material herein and/or be otherwise included within the present compositions and/or products can include vanilla, coffee, chocolate/cocoa, cream, mint, spearmint, menthol, peppermint, wintergreen, eucalyptus, lavender, cardamom, 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). Flavoring agents may comprise components such as terpenes, terpenoids, aldehydes, ketones, esters, and the like. In some embodiments, the flavoring agent is a trigeminal sensate. As used herein, "trigeminal sensate" refers to a flavoring agent which has an effect on

the trigeminal nerve, producing sensations including heating, cooling, tingling, and the like. Non-limiting examples of trigeminal sensate flavoring agents include capsaicin, citric acid, menthol, Sichuan buttons, erythritol, and cubebol. Flavorings 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.. In some instances, the flavoring agent may be provided in a spray-dried form or a liquid form.

[0057] The flavoring agent generally comprises at least one volatile flavor component. As used herein, "volatile" refers to a chemical substance that forms a vapor readily at ambient temperatures (i.e., a chemical substance that has a high vapor pressure at a given temperature relative to a nonvolatile substance). Typically, a volatile flavor component has a molecular weight below about 400 Da, and often include at least one carbon-carbon double bond, carbon-oxygen double bond, or both. In one embodiment, the at least one volatile flavor component comprises one or more alcohols, aldehydes, aromatic hydrocarbons, ketones, esters, terpenes, terpenoids, or a combination thereof. Non-limiting examples of aldehydes include vanillin, ethyl vanillin, p-anisaldehyde, hexanal, furfural, isovaleraldehyde, cutninaldehyde, benzaldehyde, and citronellal. Non-limiting examples of ketones include 1-hydroxy-2-propanone and 2-hydroxy-3-methyl-2-cyclopentenone-1-one. Non-limiting examples of esters include allyl hexanoate, ethyl heptanoate, ethyl hexanoate, isoamyl acetate, and 3-methylbutyl acetate. Non-limiting examples of terpenes include sabinene, limonene, gamma-terpinene, beta-farnesene, nerolidol, thujone, myrcene, geraniol, nerol, citronellol, linalool, and eucalyptol. In one embodiment, the at least one volatile flavor component comprises one or more of ethyl vanillin, cinnamaldehyde, sabinene, limonene, gamma-terpinene, beta-farnesene, or citral. In one embodiment, the at least one volatile flavor component comprises ethyl vanillin.

[0058] The amount of flavoring agent utilized in the mixture can vary, but is typically up to about 10 weight percent, and certain embodiments are characterized by a flavoring agent content of at least about 0.1 weight percent, such as about 0.5 to about 10 weight percent, about 1 to about 6 weight percent, or about 2 to about 5 weight percent, based on the total weight of the mixture.

Tobacco material

[0059] In some embodiments, the present compositions and/or products 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. rustic a, 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.. 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).

[0060] *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 generic 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..

[0061] 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.

[0062] Various parts or portions of the plant of the *Nicotiana* species can be included within a mixture 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 mixture 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).

[0063] 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.. 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..

[0064] 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 weight percent or less than about 5 weight percent. 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.

[0065] 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 weight percent to less than about 5 weight percent. 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 weight percent, often less than about 20 weight percent, and frequently less than about 15 weight percent.

[0066] 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. 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). Certain types of tobaccos can be subjected to alternative types of curing processes, such as fire curing or sun curing.

[0067] 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.

[0068] 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.

[0069] 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.. 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.. In certain embodiments, this type of treatment is useful where the original tobacco material is subjected to heat in the processes previously described.

[0070] 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. For example, bleached tobacco material produced by various whitening methods using various bleaching or oxidizing agents and oxidation catalysts can be used. Example oxidizing agents include peroxides (e.g., hydrogen peroxide), chlorite salts, chlorate salts, perchlorate salts, hypochlorite salts, ozone, ammonia, potassium permanganate, and combinations thereof. Example oxidation catalysts are titanium dioxide, manganese dioxide, and combinations thereof. Processes for treating tobacco with bleaching agents are discussed, for example, in US Patent 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.

[0071] In some embodiments, the whitened tobacco material 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 whitened tobacco material 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.

[0072] In some embodiments, the whitened tobacco material can be characterized as lightened in color (e.g., "whitened") in comparison to an untreated tobacco material. White colors are often defined with reference to the International Commission on Illumination's (CIE's) chromaticity diagram. The whitened tobacco material can, in certain embodiments, be characterized as closer on the chromaticity diagram to pure white than an untreated tobacco

material.

[0073] 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.. 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.

[0074] 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) and 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 0% by weight of tobacco material.

Further Additives

[0075] In some embodiments, one or more further additives can be included in the disclosed compositions and/or products. For example, the compositions 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. Specific types of further additives that may be included are further described below.

[0076] In some embodiments, the compositions and products may include a content of water. The water content (or total moisture content) of the composition within the product, prior to use by a consumer of the product, may vary according to the desired properties. Typically, the composition, as present within the product prior to insertion into the mouth of the user, can comprise less than 60%, less than 50%, less than 40%, less than 30%, less than 20%, less than 10%, or less than 5% by weight of water. For example, total water content in the composition and/or product may be in the range of about 0.1% to about 60%, about 1% to about 50%, about 1.5% to about 40%, or about 2% to about 25% by weight of water. In some

embodiments, the compositions and products may include at least 1%, at least 2%, at least 5%, at least 10%, or at least 20% by weight water. As already described above, the water content in some embodiments, may be at least partially related to the content of other components of the composition, such as a nicotine content or a content of another active agent. Likewise, water content (or total moisture content) may vary in relation to the use of a binder component, as otherwise described below. For example, water content or total moisture content may be in the range of about 10% to about 40%, about 15% to about 35%, or about 15% to about 30% by weight based on the total weight of the composition or product.

[0077] In some embodiments, the compositions and products may include a content of one or more organic acids. 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 ingredient as opposed to merely being inherently present as a component of another ingredient (e.g., the small amount of organic acid which may inherently be present in an ingredient such as a tobacco material). In some embodiments, the one or more organic acids are added neat (i.e., in their free acid, native solid or liquid form) or as a solution in, e.g., water. In some embodiments, the one or more organic acids are added in the form of a salt, as described herein below.

[0078] 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, 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 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.

[0079] 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, benzene sulfonic acid, and *p*-toluenesulfonic acid. In some embodiments, the organic acid is citric acid, malic acid, tartaric acid, octanoic acid, benzoic acid, a toluic acid, salicylic acid, or a combination thereof. In some embodiments, the

organic acid is benzoic acid. In some embodiments, the organic acid is citric acid. In alternative embodiments, a portion, or even all, of the organic acid may be added in the form of a salt with an alkaline component, which may include, but is not limited to, nicotine. Non-limiting examples of suitable salts, *e.g.,* for nicotine, include formate, acetate, propionate, isobutyrate, butyrate, alpha-methylbutyate, isovalerate, beta-methylvalerate, caproate, 2-furoate, phenylacetate, heptanoate, octanoate, nonanoate, oxalate, malonate, glycolate, benzoate, tartrate, levulinate, ascorbate, fumarate, citrate, malate, lactate, aspartate, salicylate, tosylate, succinate, pyruvate, and the like.

[0080] The amount of organic acid present in the compositions may vary. Generally, the compositions can comprise from 0 to about 10% by weight of organic acid, present as one or more organic acids, based on the total weight of the mixture.

[0081] In some embodiments, the compositions may further comprise a salt (e.g., alkali metal salts), typically employed in an amount sufficient to provide desired sensory attributes to the compositions and products. Non-limiting examples of suitable salts include sodium chloride, potassium chloride, ammonium chloride, flour salt, and the like. When present, a representative amount of salt is about 0.5 percent by weight or more, about 1.0 percent by weight or more, or at about 1.5 percent by weight or more, but will typically make up about 10 percent or less of the total weight of the composition or product, or about 7.5 percent or less or about 5 percent or less (e.g., about 0.5 to about 5 percent by weight).

[0082] The compositions and products also may include one or more sweeteners. 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, mannose, galactose, lactose, isomaltulose, 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). When present, a representative amount of sweetener may make up from about 0.1 to about 20 percent 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% of the composition or product on a weight basis, based on the total weight of the composition or product.

[0083] In some embodiments, the compositions and products may include one or more binding agents. 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 povidone, sodium alginate, starch-based binders, pectin, carrageenan, pullulan, zein, and the

like, and combinations thereof. In some embodiments, the binder comprises pectin or carrageenan or combinations thereof.

[0084] The amount of binder utilized can vary, but is typically up to about 30 weight percent, and certain embodiments are characterized by a binder content of at least about 0.1% by weight, such as about 1 to about 30% by weight, or about 5 to about 10% by weight, based on the total weight of the composition or product. As described above, one or more binders may be particularly useful in composition having a relatively moderate amount of moisture, such as in the range of about 15% to about 30% by weight water based on the total weight of the composition or product. Such compositions may be particularly suited for use with certain active agents that have improved stability and/or improved release when contained within a product having an overall moderate moisture content.

[0085] 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. When present, natural gum binder materials are typically present in an amount of up to about 5% by weight, for example, from about 0.1, 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%, to about 2, about 3, about 4, or about 5% by weight, based on the total weight of the composition or product.

[0086] In certain embodiments, one or more humectants may be employed in the compositions. 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 compositions. Further, in some instances, the humectant may impart desirable flow characteristics to the composition for depositing in a mold. When present, a humectant will typically make up about 5% or less of the weight of the composition or product (e.g., from about 0.5 to about 5% by weight). When present, a representative amount of humectant is about 0.1% to about 1% by weight, or about 1% to about 5% by weight, based on the total weight of the composition or product.

[0087] In certain embodiments, the compositions 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. Where present, the buffering agent is typically present in an amount less than about 5 percent based on the weight of the compositions or products, for example, from about 0.5% to about 5%, such as, *e.g.,* from about 0.75% to about 4%, from about 0.75% to about 3%, or from about 1% to about 2% by weight, based on the total weight of the compositions or products. Non-limiting examples of suitable buffers include alkali metals

acetates, glycinates, phosphates, glycerophosphates, citrates, carbonates, hydrogen carbonates, borates, or mixtures thereof. As noted above, it may be desirable in certain embodiments to provide a pH within a defined range, and the foregoing materials can be suitable for use in providing compositions and products having the desired pH range.

[0088] In some embodiments, the compositions and products may include one or more colorants. A colorant may be employed in amounts sufficient to provide the desired physical attributes to the composition or product. Examples of colorants include various dyes and pigments, such as caramel coloring and titanium dioxide. The amount of colorant utilized in the compositions or products can vary, but when present is typically up to about 3 weight percent, 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 or product.

[0089] Examples of even further types of additives that may be used in the present compositions and products include thickening or gelling agents (e.g., fish gelatin), emulsifiers, oral care additives (e.g., thyme oil, eucalyptus oil, and zinc), 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.. 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 mixture, with an example range of up to about 10% by weight, based on total weight of the mixture (e.g., about 0.1 to about 5% by weight).

[0090] In one or more embodiments, the present compositions and products may include one or more complexing agents, such as a cyclodextrin. Non-limiting examples of suitable cyclodextrins used in compositions include gamma cyclodextrin and hydroxypropyl cyclodextrin. Due to their cyclic structure, cyclodextrins can function as a host, for example, to incorporate flavor material and/or active ingredients in the form of an inclusion complex into compositions. Without wishing to be bound to theory, the incorporated flavor and/or active ingredient may be released as the result of thermal degradation and/or transfer to saliva once the composition is placed in the high moisture, oral cavity of the user. In one embodiment of the present disclosure, at least a portion of the at least one active agent is bound to the cyclodextrin. In some embodiments, when a cyclodextrin or similar complexing agent is utilized, it may be beneficial to limit the total moisture content of the overall composition or product. Reduced moisture may improve product stability, and it thus can be useful for the total moisture content of compositions and products including a cyclodextrin or other complexing agent to be in the range of about 5% to about 30%, about 10% to about 30%, or about 15% to about 30% by weight based on the total weight of the composition or product.

[0091] 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 mixture). Furthermore, the aforementioned types of additives may be encapsulated as provided in the final product or mixture. Exemplary encapsulated additives are described, for example, in WO2010/132444 to Atchley.

Particles

[0092] In some embodiments, any one or more of a filler component, a tobacco material, and the overall oral product described herein can be described as a particulate material. 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.

[0093] 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).

[0094] 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 1000 µm, such as 500 µm, such as 400 µm, such as 300 µm.

[0095] In some embodiments, any particulate material referenced herein (*e.g.,* filler component, tobacco material, and the overall oral product) can be characterized as having at least 50% by weight of particles with a particle size as measured by sieve analysis of no greater than about 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 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 1000 µm, such as no greater than about 500 µm, such as no greater than about 400 µm, such as no greater than about 350 µm, such as no greater than about 300 µm.

[0096] 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 1000 µm, such as from about 0.05 µm to about 750 µm, such as from about 0.1 µm to about 500 µm, such as from about 0.25 µm to about 500 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 10 μm to about 400 μm, such as from about 50 μm to about 350 μm, such as from about 100 μm to about 350 μm, such as from about 200 μm to about 300 μm.

Preparation

[0097] The manner by which the various components of the present compositions are combined may vary. As such, an overall mixture of various components with e.g., powdered mixture 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 mixture, or simply mixed together with all other liquid or dry ingredients. The various components may be contacted, combined, or mixed together using any mixing technique or equipment known in the art. Any mixing method that brings the mixture 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. In some embodiments, the components forming the mixture are prepared such that the mixture thereof may be used in a starch molding process for forming the mixture. Manners and methods for formulating mixtures 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..

Configured for oral use

[0098] Provided herein is a product configured for oral use. The term "configured for oral use" as used herein means that the product 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 mixture (e.g., flavoring agents and/or nicotine) to pass into the mouth of the user. In certain embodiments, the product is adapted to deliver releasable components to a user through mucous membranes in the user's mouth and, in some instances, said releasable component is an active ingredient (including, but not limited to, for example, nicotine) that can be absorbed through the mucous membranes in the mouth when the product is used.

[0099] Products configured for oral use as described herein may take various forms, including gels, pastilles, gums, lozenges, powders, and pouches. Gels can be soft or hard. Certain

products configured for oral use are in the form of pastilles. As used herein, the term "pastille" refers to a dissolvable oral product made by solidifying a liquid or gel mixture so that the final product is a somewhat hardened solid gel. The rigidity of the gel is highly variable. Certain products of the disclosure are in the form of solids. Certain products can exhibit, for example, one or more of the following characteristics: crispy, granular, chewy, syrupy, pasty, fluffy, smooth, and/or creamy. In certain embodiments, the desired textural property can be selected from the group consisting of adhesiveness, cohesiveness, density, dryness, fracturability, graininess, gumminess, hardness, heaviness, moisture absorption, moisture release, mouthcoating, roughness, slipperiness, smoothness, viscosity, wetness, and combinations thereof.

[0100] The products comprising the mixtures of the present disclosure may be dissolvable. As used herein, the terms "dissolve," "dissolving," and "dissolvable" refer to mixtures having aqueous-soluble components that interact with moisture in the oral cavity and enter into solution, thereby causing gradual consumption of the product. According to one aspect, the dissolvable product is capable of lasting in the user's mouth for a given period of time until it completely dissolves. Dissolution rates can vary over a wide range, from about 1 minute or less to about 60 minutes. For example, fast release mixtures typically dissolve and/or release the active substance 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). 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 mixture. In some embodiments, the product can be meltable as discussed, for example, in US Patent App. Pub. No. 2012/0037175 to Cantrell et al. In other embodiments, the products do not dissolve during the product's residence in the user's mouth.

[0101] The product comprising the composition of the present disclosure is in the form of a mixture disposed within a moisture-permeable container (e.g., a water-permeable pouch). Such mixtures in the water-permeable pouch format are typically used by placing one pouch containing the mixture 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 mixture therein (e.g., flavoring agents and/or active ingredients, such as nicotine) to pass through e.g., the water-permeable pouch and provide the user with flavor and satisfaction, and the user is not required to spit out any portion of the mixture. After about 10 minutes to about 60 minutes, typically about 15 minutes to about 45 minutes, of use/enjoyment, substantial amounts of the mixture have been ingested by the human subject, and the pouch may be removed from the mouth of the human subject for disposal.

[0102] Accordingly, in certain embodiments, the mixture as disclosed herein and any other components noted above are combined within a moisture-permeable packet or pouch that acts as a container for use of the mixture to provide a pouched product configured for oral use. Certain embodiments of the disclosure will be described with reference to the Figure, and

these described embodiments involve snus-type products having an outer pouch and containing a mixture as described herein. As explained in greater detail below, such embodiments are provided by way of example only, and the pouched products of the present disclosure can include the composition in other forms. The mixture/construction of such packets or pouches, such as the container pouch **102** in the embodiment illustrated in the Figure, may be varied. Referring to the Figure, there is shown a first 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 a composition as described herein. The pouched product **100** may be an example of a product as described herein formed at least in part from the described compositions.

[0103] Suitable packets, pouches or containers 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 mixture 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 mixture readily diffuse through the pouch and into the mouth of the user.

[0104] 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.. 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.

[0105] An example 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 mixture each may undergo complete dispersion within the mouth of the user during normal conditions of use, and hence the pouch and mixture both may be ingested by the user. Other examples of pouch materials may be manufactured using water dispersible film forming materials (e.g., binding agents such as alginates, 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 mixture 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.

[0106] The amount of material contained within each product unit, for example, a pouch, may vary. In some embodiments, the weight of the mixture 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 g, or from about 200 to about 700 mg. In some smaller embodiments, the weight of the mixture 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.

[0107] 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..

[0108] Compositions and products according to the present disclosure may be adapted to or configured to provide a desired release profile in relation to one or more of the releasable materials provided therewith. In some embodiments, a desired release rate may particularly relate to a flavor material. In other embodiments, a desired release rate may particularly relate to an active agent.

[0109] 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.

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PATENTKRAV

1. Oralt poseprodukt omfattende en oral sammensætning i en vandpermeabel pose, hvor den orale sammensætning omfatter:

mindst ét aktivstof;

mindst én cellulosebaseret fyldstofbestanddel og

vand i en tilstrækkelig mængde, således at den orale sammensætning har et totalt fugtindhold på 20 til 45 vægt-% baseret på den orale sammensætnings totalvægt,

hvor den orale sammensætning er helt fri for tobaksmaterialer eller omfatter mindre end 1 vægt-% tobaksmateriale, bortset fra en hvilken som helst nikotinbestanddel ved tilstedeværelse, og

hvor sammensætningen ikke omfatter et lipid.

2. Oral sammensætning ifølge krav 1, hvor alt af det mindst ene aktivstof eller en del af det mindst ene aktivstof bindes til samtlige af den mindst ene fyldstofbestanddel eller en del af den mindst ene fyldstofbestanddel.

3. Oral sammensætning ifølge krav 1, hvor den orale sammensætning endvidere omfatter et bindemiddel valgt fra en gruppe bestående af povidon, natriumalginat, stivelsesbaserede bindemidler, pektin, carrageenan, pullulan, zein, gummi og kombinationer deraf.

4. Oral sammensætning ifølge krav 1, hvor det mindst ene aktivstof vælges fra en gruppe bestående af plantestoffer, stimulanser, aminosyrer, vitaminer, cannabinoider, cannabimimetika, terpener, nutraceuticals og kombinationer deraf.

5. Oral sammensætning ifølge krav 1, hvor det mindst ene aktivstof er en nikotinbestanddel, og navnlig hvor nikotinbestanddelen er én eller både af nikotinfri base og et nikotinsalt.

6. Oral sammensætning ifølge krav 5, hvor nikotinbestanddelen er til stede i en mængde, således at et vægt/vægtforhold mellem nikotinbestanddelen og det totale fugtindhold er 0,01 til 0,2, og navnlig

hvor nikotinbestanddelen er til stede i en mængde, således at et vægt/vægtforhold mellem nikotinbestanddelen og det totale fugtindhold er 0,01 til 0,1, og navnlig

hvor nikotinbestanddelen er til stede i en mængde, således at et vægt/vægtforhold mellem nikotinbestanddelen og det totale fugtindhold er 0,03 til 0,08.

7. Oral sammensætning ifølge krav 5, hvor nikotinbestanddelen er til stede i en mængde, der er større end 2 vægt-% baseret på den orale sammensætnings totalvægt, og navnlig hvor nikotinbestanddelen er til stede i en mængde på 3 til 10 vægt-% baseret på den orale sammensætnings totalvægt.

8. Oral sammensætning ifølge krav 7, hvor den orale sammensætning har en pH-værdi, der er højere end 7.

9. Oral sammensætning ifølge krav 5, hvor nikotinbestanddelen er til stede i en mængde på mindre end 1 vægt-% baseret på den orale sammensætnings totalvægt, og navnlig hvor nikotinbestanddelen er til stede i en mængde på 0,01 til 0,9 vægt-% baseret på den orale sammensætnings totalvægt.

10. Oral sammensætning ifølge krav 1, hvor den orale sammensætning endvidere omfatter et cyclodextrin, og navnlig
hvor alt af det mindst ene aktivstof eller en del af det mindst ene aktivstof bindes til cyclodextrinet.

11. Oral sammensætning ifølge et hvilket som helst af kravene 1 til 10, hvor den orale sammensætning omfatter et hvidt tobaksmateriale i en mængde på mindre end 1 vægt-%, bortset fra en hvilken som helst nikotinbestanddel til stede i den orale sammensætning, baseret på den orale sammensætnings totalvægt.

DRAWINGS

Drawing

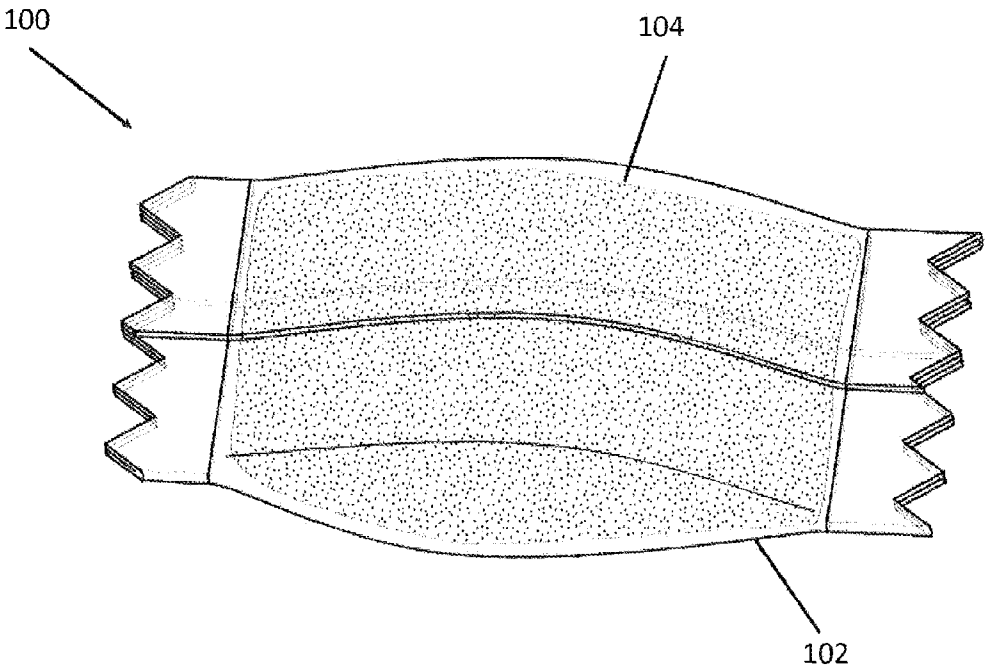


FIG. 1