

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 November 2006 (30.11.2006)

PCT

(10) International Publication Number
WO 2006/127772 A2

(51) International Patent Classification:
A24F 47/00 (2006.01)

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(21) International Application Number:
PCT/US2006/020025

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(22) International Filing Date: 24 May 2006 (24.05.2006)

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/684,636 25 May 2005 (25.05.2005) US
11/344,848 31 January 2006 (31.01.2006) US

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(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TOBACCO COMPOSITIONS

(57) Abstract: The invention features tobacco compositions and methods of their use and manufacture. Compositions of the invention may be based on a variety of technologies. Technologies include films, tabs, shaped parts, gels, consumable units, insoluble matrices, and hollow shapes. In addition to tobacco, compositions may also contain flavors, colors, and other additives as described herein. Compositions may also be orally disintegrable. Exemplary compositions and methods of their manufacture are described herein.



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TOBACCO COMPOSITIONS

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FIELD OF THE INVENTION

The invention relates to the field of tobacco products.

SUMMARY OF THE INVENTION

10 The invention features tobacco compositions and methods of their use and manufacture. Compositions of the invention may be based on a variety of technologies. Technologies include films, tabs, shaped parts, gels, consumable units, insoluble matrices, hollow shapes, and such compositions disposed on a holding device. In addition to tobacco, compositions may also contain flavors, 15 colors, and other additives as described herein. Compositions may also be orally disintegrable. Exemplary compositions and methods of their manufacture are described herein.

For example, any composition described herein may include a flavor or flavor masking agent. Exemplary flavors include licorice, kudzu, hydrangea, 20 Japanese white bark magnolia leaf, chamomile, fenugreek, clove, menthol, Japanese mint, aniseed, cinnamon, herb, wintergreen, cherry, berry, apple, peach, Dramboui, bourbon, scotch, whiskey, spearmint, peppermint, lavender, cardamon, apium graveolens, cascarilla, nutmeg, sandalwood, bergamot, geranium, honey essence, rose oil, vanilla, lemon oil, orange oil, cassia, 25 caraway, cognac, jasmin, ilangilang, sage, fennel, piment, ginger, anise, coriander, coffee, coconut, grapefruit, lime, mandarin, pineapple, strawberry, raspberry, mango, passion fruit, kiwi, pear, apricot, grape, banana, cranberry, blueberry, black currant, red currant, gooseberry, lingon berries, thyme, basil, camille, valerian, parsley, camomile, tarragon, lavender, dill, cumin, salvia, 30 aloe vera, balsam, eucalyptus, or a mint oil from any species of the genus *Mentha*. Other flavors are described herein.

Any composition of the invention may also include:

Sweetener such as sucrose, sucralose, acesulfame potassium, aspartame, saccharine, cyclamates, lactose, tagatose, sucrose, glucose, fructose, sorbitol, mannitol, and combinations thereof. Sugar sweeteners generally include
5 saccharide-containing components such as, but not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like or mixtures thereof. Sorbitol can be used as a sugarless sweetener. Additionally, sugarless sweeteners can include, but are not limited to, other sugar alcohols such as mannitol, xylitol, hydrogenated
10 starch hydrolysates, maltitol, and the like or mixtures thereof. High intensity artificial sweeteners can also be used in combination with the above. Preferred artificial sweeteners include, but are not limited to sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, and the like or mixtures
15 thereof.

Surfactant such as nonionic surfactants which may be used in the present invention include glycerol-polyethylene glycol oxystearate, polyoxyethylene esters or sorbitol laurate esters, such as polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monoisostearate, polyoxyethylene sorbitan
20 monostearate, polyoxyethylene sorbitan monooleate, polyoxyethylene or sorbitol laurate esters including polysorbates, and block polymers of polyoxyethylene and polyoxypropylene and the like or mixtures thereof. When a combination of surfactants is used, the first component may be a polyoxyethylene sorbitan fatty acid ester or a α -hydro- ω -hydroxypoly
25 (oxyethylene)poly(oxypropylene)poly(oxyethylene) block copolymer, while the second component may be a polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative. Amphoteric, amphipathic/amphiphilic surfactants, non-ionic surfactants and/or cationic surfactants can be used in the compositions of the present invention. Suitable non-ionic surfactants include,
30 for example, polyoxyethylene compounds, lecithin, ethoxylated alcohols,

ethoxylated esters, ethoxylated amides, polyoxypropylene compounds, propoxylated alcohols, ethoxylated/propoxylated block polymers, propoxylated esters, alkanolamides, amine oxides, fatty acid esters of polyhydric alcohols, ethylene glycol esters, diethylene glycol esters, propylene glycol esters, glycerol esters, polyglycerol fatty acid esters, sorbitan esters, sucrose esters, glucose (dextrose) esters, simethicone, and the like or mixtures thereof.

Plasticizer such as glycerine, propylene glycol, polyethylene glycol, sorbitol/mannitol, acetylated monoglycerides, monoacetin, diacetin, triacetin, 1,3 butane diol, and the like or mixtures thereof.

Filler such as starch, microcrystalline cellulose, wood pulp, disc refined wood pulp, insoluble fiber, soluble fiber, calcium carbonate, dicalcium phosphate, calcium sulfate, a clay, and the like or mixtures thereof.

Lubricant such as stearic acid and a stearate such as magnesium stearate, light anhydrous silicic acid, talc, sodium lauryl sulfate and the like, or mixtures thereof or a wax such as lecithin, glycerol monostearate, propylene glycol monostearate, cocoa butter, white petrolatum, polyethylene glycol and the like, or mixtures thereof.

Preservative such as methyl paraben, ethyl paraben, propyl paraben, potassium sorbate, sodium benzoate, sodium bisulfite and the like and the like, or mixtures thereof.

Stabilizer such as ascorbic acid, monostearyl citrate, BHT, BHA, citric acid, sodium citrate, acetic acid and the like, or mixtures thereof.

Coloring agent such as vegetable dyes or other food grade dyes, water soluble chlorophyll and the like, or mixtures thereof.

Any composition described herein may further include a coating, e.g., matte or glossy. The coating preferably includes a color, flavor, sweetener, or flavor masking agent. The coating may also include a different flavor, color, or rate of disintegration from the format in the composition. The coating may also include tobacco. Exemplary flavors are described herein.

Any composition described herein may further include a printed pattern, e.g., in a logo. A printed pattern may include a color, tobacco, a flavor, sweetener, or flavor masking agent. The surface of any composition described herein may also include a pattern in relief.

- 5 Tobacco included in any composition may be a powder, granules, shreds, or perceived to be soluble or insoluble in the mouth.

Any composition described herein may further include flakes, e.g., containing tobacco or a plurality of flavors or colors.

- 10 Any composition of the invention may be formed in a shape suitable for application in the mouth. A composition of the invention may further provide tobacco satisfaction, e.g., over a period of 1 s to 30 minutes.

The invention also features a method for obtaining tobacco satisfaction by placing at least a portion of any composition as described herein in the mouth.

- 15 The invention also features methods for making compositions as described herein. Any of these methods may further include adding a coating to the composition, e.g., by spraying, brushing, roll coating, doctor bar casting, slot coating, extrusion coating, or hot melt deposition. Any of the methods may also include printing a pattern on the composition, e.g., by offset,
20 flexographic, gravure, ink jet, laser, or screen printing. In addition, the methods of making compositions may include adding a flavor, color, flavor masking agent, or any other ingredient described herein to the format or composition.

- By "format" is meant an ingredient or compilation of ingredients, as
25 provided herein, in a composition, for example, a polymer, gum, hydrocolloid, binder, carrier, or agent. Water-soluble synthetic polymer formats may include polyvinyl pyrrolidone, water soluble cellulose, polyvinyl alcohol, ethylene maleic anhydride copolymer, methylvinyl ether maleic anhydride copolymer, acrylic acid copolymers, anionic polymers of methacrylic acid and
30 methacrylate, cationic polymers with dimethyl-aminoethyl ammonium

functional groups, polyethylene oxides, water soluble polyamide and polyester and the like, or mixtures thereof. Preferred water-soluble polymer formats include water-soluble cellulose-derivatives, e.g., hydroxypropylmethyl cellulose, hydroxyethyl cellulose, or hydroxypropyl cellulose, or mixtures thereof. Additional formats include carboxymethyl cellulose, sodium alginate, polyethylene glycol, natural gums like xanthan gum, tragacantha, guar gum, acacia gum, arabic gum, water-dispersible polyacrylates like polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers. The format may be a mixture, a blend with other formats, or a block-polymer. Other exemplary formats are described herein.

By "derivative" is meant a chemical substance related structurally to another substance and theoretically derivable from it. For example, formats may be alkylated, e.g., methylated, ethylated, propylated, or butylated, hydroxylated, carboxylated, acylated, e.g., acetylated, cross-linked, aminated, phosphorylated, sulfated, halogenated, e.g., fluoro, bromo, chloro, or iodo, or hydrogenated.

By "tobacco" is meant any part, e.g., leaves, flowers, roots, and stems, of any member of the genus *Nicotiana*. Exemplary species of tobacco include *N. rustica* and *N. tabacum* (e.g., LA B21, LN KY171, TI 1406, Basma, Galpao, Perique, Beinhart 1000-1, and Petico). Other species include *N. acaulis*, *N. acuminata*, *N. acuminata* var. *multiflora*, *N. africana*, *N. alata*, *N. amplexicaulis*, *N. arentsii*, *N. attenuata*, *N. benavidesii*, *N. benthamiana*, *N. bigelovii*, *N. bonariensis*, *N. cavicola*, *N. clevelandii*, *N. cordifolia*, *N. corymbosa*, *N. debneyi*, *N. excelsior*, *N. forgetiana*, *N. fragrans*, *N. glauca*, *N. glutinosa*, *N. goodspeedii*, *N. gossei*, *N. hybrid*, *N. ingulba*, *N. kawakamii*, *N. knightiana*, *N. langsдорffii*, *N. linearis*, *N. longiflora*, *N. maritima*, *N. megalosiphon*, *N. miersii*, *N. noctiflora*, *N. nudicaulis*, *N. obtusifolia*, *N. occidentalis*, *N. occidentalis* subsp. *hesperis*, *N. otophora*, *N. paniculata*, *N. pauciflora*, *N. petunioides*, *N. plumbaginifolia*, *N. quadrivalvis*, *N. raimondii*, *N. repanda*, *N. rosulata*, *N. rosulata* subsp. *ingulba*, *N. rotundifolia*, *N.*

setchellii, *N. simulans*, *N. solanifolia*, *N. spegazzinii*, *N. stocktonii*, *N. suaveolens*, *N. sylvestris*, *N. thyrsiflora*, *N. tomentosa*, *N. tomentosiformis*, *N. trigonophylla*, *N. umbratica*, *N. undulata*, *N. velutina*, *N. wigandioides*, and *N. x sanderae*. The tobacco may be whole, shredded, cut, cured, aged, fermented, or otherwise processed, e.g., granulated or encapsulated. Tobacco may also be in the form of finished products, including but not limited to any non-combustible tobacco that is orally consumed, e.g., smokeless tobacco. Such smokeless tobacco includes snuff (moist or dry), chewing tobacco, loose tobacco, pouched tobacco, and the like, or any form contained herein. The term also includes an extract of tobacco including two or more tobacco organoleptic components.

By "tobacco satisfaction," in this case, is meant the experience associated with tobacco organoleptic components and added flavor components that are released in the mouth when using a smokeless tobacco. An adult consumer who chooses to use a smokeless tobacco product purchases a smokeless tobacco product typically according to their individual preference; such a preference includes, without limitation, flavor, cut of tobacco, form, ease of use, and packaging.

By "organoleptic" is meant relating or contributing to the integrated sensory perception by the consumer that includes, for example, any combination of aroma, fragrance, flavor, taste, odor, mouth feel, or the like.

By "non-combustible" is meant does not combust during ordinary usage.

By "parts" is meant one of several or many equal units of which something is composed or into which it is divisible. Unless otherwise noted, parts are by weight.

Compositions described herein are advantageous from the perspective of size, ease of use, and controlled rate of disintegration.

All percentages are by weight unless otherwise noted.

Other features and advantages will be apparent from the following description and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic representation of flavored tobacco strips (films). The strips are thin and contain tobacco. When placed in the mouth of a user, the strip disintegrates immediately, e.g., 0.5-30 seconds, with a burst of flavor.

5 In addition, the strips may alternatively disintegrate in 30 sec to 1 minute, 30 sec to 3 minutes, 30 sec to 5 minutes, 30 seconds to 7 minutes or 30 sec to 10 minutes depending on the composition. The tobacco strips may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors, as described herein. A tobacco strip may contain a colored band or other indicia

10 for aesthetic purposes that are indicative of the flavor.

Figures 2A and 2B are schematic representations of flavored tobacco bursts (tabs), which are small, fast-disintegrating, round pieces containing tobacco. When placed in the mouth of a user, a tobacco burst begins to disintegrate immediately, providing flavor to the user. The tobacco bursts may

15 be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco burst may contain colored spots or other indicia for aesthetic purposes that are indicative of the flavor. Figure 2B shows a side view of a tobacco burst. The bursts may be superfast disintegrating (30 sec – 2 minutes), fast disintegrating (1 minute – 3 minutes) slower disintegrating (2

20 minutes to 5 minutes), slow disintegrating (4 minutes – 10 minutes), or effervescent in nature.

Figures 3A and 3B are schematic representations of tobacco hard pieces (tabs), which are smooth, long-lasting, and contain tobacco (e.g., flavored tobacco), and are placed in the mouth of a user. Tobacco hard pieces may be

25 flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco hard piece may contain colored spots or other indicia for aesthetic purposes that are indicative of the flavor. Figure 3B shows a side view of a tobacco hard piece.

Figures 4A and 4B are schematic representations of effervescent tobacco pieces which contain tobacco, and a user places them in the mouth.

Effervescent tobacco pieces may be flavored, for example, with wintergreen, cinnamon, mint, and/or flavors. An effervescent tobacco piece may contain a colored region or other indicia for aesthetic purposes that are indicative of the flavor. Figure 4B shows a side view of an effervescent tobacco piece.

Figures 5A and 5B are schematic representations of tobacco duets (tabs), which have a hard outer layer and a soft inner layer, or vice versa. The hard outer layer contains tobacco that disintegrates in the mouth of a user. The soft inner layer contains flavor (e.g., breath freshening agents). Tobacco duets may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco duet may contain colored spots or other indicia for aesthetic purposes that are indicative of the flavor. Figure 5B shows a side view of a tobacco duet.

Figures 6A and 6B are schematic representations of tobacco duos (tabs), which have a hard outer layer and a soft center, or vice versa. The outer layer may include flavors such breath freshening agents, and the center contains tobacco. The tobacco duos disintegrate when placed in the mouth of a user. Tobacco duos may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco duo may contain colored spots or other indicia for aesthetic purposes that are indicative of the flavor. Figure 6B shows a cross section of a tobacco duo.

Figures 7A and 7B are schematic representations of tobacco toothpicks, which are similar in size and shape to a wooden toothpick and include tobacco. The tobacco toothpick is placed in the mouth of a user and slowly disintegrates in about the time it takes to smoke a cigarette (e.g., 3 - 10 minutes). In a similar embodiment, the tobacco toothpick may not disintegrate yet be porous enough to allow diffusion of tobacco and flavor while the toothpick remains structurally intact. The tobacco toothpicks may be flavored, for example, with

wintergreen, cinnamon, mint, and/or other flavors. A tobacco toothpick may contain a colored band or other indicia for aesthetic purposes that are indicative of the flavor. Figure 7B shows a side view of a tobacco toothpick.

5 Figures 8A and 8B are schematic representations of tobacco gel chews, which contain tobacco and slowly disintegrate in the mouth of a user, for example, when chewed. Tobacco gel chews may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco gel chew may be colored for aesthetic purposes to indicate the flavor. Figure 8B shows a side view of a tobacco gel chew.

10 Figures 9A and 9B are schematic representations of tobacco gel beads, which are small, soft beads with a liquid center containing tobacco. The user places a bead in the mouth, causing it to melt. Upon melting, the bead releases tobacco and optionally flavor (e.g., wintergreen, cinnamon, mint, and/or other flavors). A tobacco gel bead may be colored for aesthetic purposes to indicate the flavor. Figure 9B shows a cross section of a tobacco gel bead.

15 Figures 10A and 10B are schematic representations of disintegrable tobacco packs (consumable units), which can be placed in the mouth of a user (e.g., on the side of the mouth). The thin, outer layer may provide flavor to the user as it disintegrates. The inside contains tobacco that disintegrates completely. The disintegrable tobacco packs can be savored for about as long as it takes to smoke a cigarette (e.g., 3 - 10 minutes) or for a shorter time, and may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A disintegrable tobacco pack may contain colored spots or other indicia for aesthetic purposes that are indicative of the flavor. Figure 10B shows a side view of a disintegrable tobacco pack. In an alternative embodiment, the thin, outer layer does not disintegrate but is porous, thereby allowing the contents contained therein to diffuse out over time.

Figures 11A and 11B are schematic representations of tobacco packs (consumable units), which are smoke-free tobacco products including a small, insoluble packet filled with tobacco and optionally other flavors. The packet is placed in the mouth of a user (e.g., on the side of the mouth). Tobacco packs are typically used for 5 – 15 minutes, e.g., about 10 minutes, and are discarded after use. The tobacco packs may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco pack may contain a stripe or other indicia for aesthetic purposes that are indicative of the flavor. Figure 11B shows a side view of a tobacco pack.

Figures 12A and 12B are schematic representations of tobacco sticks, which contain tobacco and are slender and smooth with dimensions similar to a cigarette. They disintegrate slowly (e.g., in 3 - 10 minutes) when placed into the mouth of a user. Tobacco sticks may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco stick may contain a colored band or other indicia for aesthetic purposes that are indicative of the flavor. Figure 12B shows a side view of a tobacco stick.

Figures 13A and 13B are schematic representations of tobacco straws, which are smooth, hollow, flexible cylinders containing tobacco (e.g., flavored tobacco). The tobacco straw is placed into the mouth of a user, and slowly (e.g., in 3 - 10 minutes) disintegrates, preferably completely. Additionally, the tobacco straw may, for example, not disintegrate in the hand of the user. The tobacco may be flavored, for example, with wintergreen, cinnamon, mint, and/or other flavors. A tobacco straw may contain a colored band or other indicia for aesthetic purposes that are indicative of the flavor. Figure 13B shows a side view of a tobacco straw.

Figures 14A and 14B are schematic representations of filled tobacco straws, which have a smooth outer layer containing tobacco (e.g., flavored tobacco) and a soft tobacco core. The smooth outer layer may, for example, not disintegrate in the hand of a user, but disintegrate when placed into the mouth of the user. The filled tobacco straws may be flavored, for example,

with wintergreen, cinnamon, mint, and/or other flavors. A filled tobacco straw may contain a colored band or other indicia for aesthetic purposes that are indicative of the flavor. Figure 14B shows a side view and an end view of a tobacco straw.

5

DETAILED DESCRIPTION OF THE INVENTION

The invention features tobacco compositions that are typically for tobacco satisfaction.

10 A. Tobacco

Tobacco useful in compositions described herein includes any raw or processed form, e.g., a powder, granule, or shred. Preferably, the tobacco is sized or made to disintegrate in the mouth (e.g., dissolve), to give the perception of dissolvability (e.g., the tobacco does not produce a tactile
15 experience in the mouth), or to be easily swallowed. Alternatively, the tobacco may be sized or made to provide a tactile experience in the mouth. Exemplary average sizes are in the range of 1 to 1000 μm , e.g., about 800, 500, 250, 100, 80, 75, 50, 25, 20, 15, 10, 8, 6, 5, 3, 2, or 1 μm or less, preferably 80 μm or less. The tobacco may also be in the form of a slurry or a flowable gel. A
20 flowable gel is a mixture of a format dissolved in water and mixed with tobacco and then mixed with a miscible solvent that prevents the complete dissolution of the format. Such a mixture causes the format to swell forming a viscous paste that is pseudoplastic and is easily dispensed from a container (e.g., a tube) with slight pressure. An exemplary tobacco is smokeless tobacco.
25 Additional tobaccos are described in U.S. Publication Nos. 2003/0094182 and 2003/0070687, International Publication No. WO 2005/041699, and U.S.S.N. 10/981,948; the disclosures of which are hereby incorporated by reference. The tobacco employed in the composition may also be prepared according to the methods of U.S. Publication No. 2004/0112394; the disclosure of which is
30 hereby incorporated by reference. Other suitable tobacco is known in the art.

Tobacco may be distributed randomly or evenly throughout a composition or concentrated in various regions thereof, e.g., in the center or on the surface.

Depending on the desired characteristics and the end use of the composition, the typical final tobacco concentration ranges from 1 percent to 99 percent by weight of the final composition, for example, at most 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, or 90%. In preferred embodiments, the composition includes around 25% tobacco.

10 B. Compositions

In general, compositions of the invention are intended for oral use or consumption. A composition containing tobacco may be manufactured using any suitable orally compatible format. The tobacco may be mixed directly with the format or otherwise supported by the format. For example, a composition may contain tobacco, e.g., as dried particles, shreds, granules, a powder, or a slurry, deposited on, mixed in, surrounded by, or otherwise combined with a format. Tobacco in compositions may or may not be, or be perceived to be, soluble. In one embodiment, the compositions are spitless tobacco compositions. Compositions may also include a mixture of forms or types of tobacco. Compositions may be foamed or dense. Foamed compositions may be rigid or flexible and may be based on water soluble, water insoluble, or thermoplastic formats. Exemplary compositions are described herein. In one embodiment, a composition of the invention is non-combustible.

Formats suitable for use in the compositions described herein include orally compatible polymers, such as cellulose derivatives (e.g., carboxymethyl cellulose (CMC), hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), hydroxypropyl methyl cellulose (HPMC), and methyl cellulose (MC)), natural polymers (e.g., starches and modified starches, konjac, collagen, inulin, soy protein, whey protein, casein, and wheat gluten), seaweed-derived polymers (e.g., carrageenan (kappa, iota, and lambda), alginates, and propylene glycol

alginate), microbial-derived polymers (e.g., xanthan, dextran, pullulan, curdlan, and gellan), extracts (e.g., locust bean gum, guar gum, tara gum, gum tragacanth, pectin (e.g., low methoxy and amidated), agar, zein, karaya, gelatin, psyllium seed, chitin, and chitosan), exudates (e.g., gum acacia (arabic) and shellac), synthetic polymers (e.g., polyvinyl pyrrolidone, polyethylene oxide, and polyvinyl alcohol). Other useful formats are known in the art, for example, see Krochta et al. *Food Technology*, 1997, 51:61-74, Glicksman *Food Hydrocolloids* CRC 1982, Krochta *Edible Coatings and Films to Improve Food Quality* Technomic 1994, *Industrial Gums* Academic 1993, Nussinovitch *Water-Soluble Polymer Applications in Foods* Blackwell Science 2003.

Depending on the desired characteristics, a composition may also include fillers (e.g., starch, microcrystalline cellulose, wood pulp (e.g., Solkafloc from International Fibers, Inc.), disc refined wood pulp, insoluble fiber, soluble fiber (e.g., Fibersol from Matsutani), calcium carbonate, dicalcium phosphate, calcium sulfate, and clays), lubricants (e.g., lecithin, stearic acid, stearates (e.g., Mg or K), and waxes (e.g., glycerol monostearate, propylene glycol monostearate, and acetylated monoglycerides)), plasticizers (e.g., glycerine, propylene glycol, polyethylene glycol, sorbitol, mannitol, monoacetin, diacetin, triacetin, and 1,3 butane diol), stabilizers (e.g., ascorbic acid and monosterol citrate, BHT, or BHA), or other compounds (e.g., vegetable oils, surfactants, and preservatives). Some compounds function as both plasticizers and lubricants.

Compositions of the invention may include flavor extracts (e.g., licorice, kudzu, hydrangea, Japanese white bark magnolia leaf, chamomile, fenugreek, clove, menthol, Japanese mint, aniseed, cinnamon, herb, wintergreen, cherry, berry, peach, apple, Dramboui, bourbon, scotch, whiskey, spearmint, peppermint, lavender, cardamon, apium graveolens, cascarilla, nutmeg, sandalwood, bergamot, geranium, honey essence, rose oil, vanilla, lemon oil, orange oil, cassia, caraway, cognac, jasmin, ilangilang, sage, fennel, piment, ginger, anise, coriander, coffee, coconut, grapefruit, lime, mandarin, pineapple,

strawberry, raspberry, mango, passion fruit, kiwi, pear, apricot, grape, banana, cranberry, blueberry, black currant, red currant, gooseberry, lingon berries, thyme, basil, camille, valerian, parsley, camomile, tarragon, lavender, dill, cumin, salvia, aloe vera, balsam, eucalyptus, or a mint oil from any species of the genus *Mentha*), flavor masking agents, bitterness receptor site blockers, receptor site enhancers, sweeteners (e.g., sucralose, acesulfame potassium (Ace-K), aspartame, saccharine, cyclamates, lactose, sucrose, glucose, fructose, sorbitol, mannitol, xylitol, erythritol, and tagatose), and other desirable additives such as chlorophyll, minerals, botanicals, or breath freshening agents.

Flavors may also be provided by solid plant matter, e.g., mint leaves, which are typically 10% flavor oils and 90% insoluble fiber. Exemplary plants further include licorice, kudzu, hydrangea, Japanese white bark magnolia, chamomile, fenugreek, clove, Japanese mint, cinnamon, herb, cherry, berry, peach, apple, lavender, cardamon, apium graveolens, cascarilla, nutmeg, sandalwood, bergamot, geranium, rose, vanilla, lemon, orange, cassia, caraway, jasmin, ilangilang, sage, fennel, piment, ginger, anise, coriander, coffee (e.g., Arabica, Brazilian Santos, Columbian Supremo, Costa Rican, Ethiopian Harrar, Hawaiian Kona, Kenya AA, Jamaica, Sumatra, Tanzanian Peaberry, Zimbabwe, or hazelnut, vanilla, amaretto, fruit, almond, Irish cream, cinnamon, or butterscotch flavored), or any species of the genus *Mentha*. Suitable plant matter further includes beans (e.g., coffee beans, vanilla beans, or cocoa nibs), nuts (e.g., almonds, peanuts, cashews, walnuts, pecans, and pistachios), or sticks (e.g., cinnamon), in whole or ground form. The plant matter may be separated from the tobacco after transference of flavor, or it may remain in combination with the tobacco, as described in WO 2005/041699.

Combinations of plant matter may also be employed.

Flavor may be provided to a composition as described herein by flavor extracts, plant matter, or a combination thereof. In addition to natural flavor extracts, flavor may also be provided by imitation, synthetic, or artificial flavor ingredients and blends containing such ingredients. Flavors may be added as a powder, an oil, in encapsulated form, or in other commercially available forms.

In certain embodiments, the composition disintegrates in the mouth. Disintegration rates of compositions may vary from 20 minutes to less than 1 minute. Fast release compositions typically disintegrate in under 2 minutes and more preferably, in 1 minute or less, e.g., less than 60 s, 50 s, 45 s, 40 s, 35 s, 30 s, 25 s, 20 s, 15 s, 10 s, 5 s, 4 s, 3 s, 2 s, or 1 s. The disintegration may occur by any mechanism, for example, dissolution, melting, mechanical disruption (e.g., from chewing), enzymatic or other chemical degradation, or disruption of the interaction between the format and tobacco. The format or tobacco itself may similarly disintegrate. The amount of time required for a composition to disintegrate may be controlled by varying the thickness of the composition and is dependent upon the type of format, other additives, and the pattern of usage. When placed in the mouth, the composition may temporarily adhere to a part of the oral mucosa. In addition, the length of time of the tobacco satisfaction may vary. This length of time may be affected by, e.g., by the rate of disintegration of a composition, the rate of extraction of organoleptic components from a composition, and the residence time of the composition in the mouth. In other embodiments, the compositions do not disintegrate over the residence period in the mouth. In such compositions, introduction of tobacco organoleptic components into the mouth may occur by partial dissolution, leaching, extraction, or mechanical disruption caused by chewing. Tobacco satisfaction may be provided from a composition over a period of at least 10 s, 30 s, 45 s, 1 min, 2 min, 3 min, 5 min, 6 min, 7 min, 8 min, 9 min, 10 min, 11 min, 12 min, 13 min, 14 min, 15 min, 30 min, or 1 h, preferably from 1 s to 10 minutes and more preferably from 30 s to 5 minutes.

Individual compositions may be sized to fit entirely in the mouth, or they may be sized to fit only partially in the mouth. Preferred cross sections of the compositions include, but are not limited to, square, circular, rectangular, elliptical, oval, and the like. Preferred dimensions may vary depending upon the serving size and ingredients. Typically, the largest dimension of a single serving is 10 cm or smaller. Alternatively, tobacco products may be made in a larger form, from which individual servings may be cut or otherwise separated, e.g., by chewing, biting, or oral disintegration. For example, a strip, or other long piece, may be placed in a container, and the consumer may remove a desired serving size. A larger composition (or orally sized piece attached to a handle) may also be partially inserted in the mouth, similar to a toothpick or cigarette, and the consumer may suck or chew on it. In one embodiment, the larger piece is orally disintegrable and may be completely consumed over a period of time.

15

C. Technologies

Films. Compositions of the invention may be formed as films that may be orally disintegrable. Such films may contain a single layer or multiple layers. A single layer film will contain tobacco, a format, and other ingredients, e.g., in a homogeneous mixture. Multilayer films may include several tobacco containing layers, e.g., with the same or different kind or size of tobacco, e.g., tobacco perceived to be soluble. Multiple layers may be laminated together. In addition, multilayer films may contain tobacco in one or more layers and other layers that contain additional ingredients, as described herein. For example, individual layers may be added for flavor, sweetness, color, rate of disintegration, or stability (e.g., during handling or during consumption). Tobacco may also be placed between two or more layers in a sandwich arrangement. One or more of the layers in the sandwich may also include tobacco. In films having multiple layers, the layers may disintegrate at the same or different rates, or a layer may not disintegrate orally. When rates

30

of disintegration differ, the composition may provide tobacco at differing times based on the layers disintegrating. Single layer films or individual layers in multilayer films may also be foamed or aerated to provide desirable physical properties or desirable dissolution or disintegration rates.

5 Films may be sized to fit in the mouth as individual servings.

Alternatively, larger films may be fabricated from which individual servings may be separated. For example, a film may be wrapped, or otherwise shaped, to form a hollow tube or straw, which in turn may be filled with additional material. In addition, a film, e.g., containing a high percentage of tobacco in
10 the range of 1% to 99% based on dry weight, may be fabricated and then used in preparation of flakes or a powder for addition to other compositions, as described herein. The preferred thickness of a film is typically less than 1 mm, e.g., less than 500, 200, 100, 50, 40, 30, 20, 10, 5, 4, 3, 2, or 1 μm ; preferably 5 to 125 μm .

15 Various methods known in the art can be used to manufacture films. The technique employed may depend on the format employed in the film. Exemplary methods include solution casting or extrusion, melt extrusion, drum drying, and calendaring. Once formed, a film may be modified, e.g., by printing or otherwise coating or decorating the surface of the film. Flavors,
20 colors, or tobacco may be added to the surface of a film by a printing, coating, or decorative process. All printing processes known in the art, e.g., offset, flexographic, gravure, ink jet, laser, screen printing, and other typical methods, may be used. Coatings or decorative patterns may be applied to the surface of the film using processes known in the art, e.g., spraying, brushing, roll coating,
25 doctor bar casting, slot coating, extrusion coating, hot melt deposition, depositing particles or flakes, and other typical methods. The film to be printed, coated, or decorated may or may not contain tobacco. One function of the printing, coating, or decorative pattern is to provide additional amounts of color, flavor, or tobacco to the film. Another function is to improve the

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dimensional stability and appearance of the film. Once the printed, coated, or decorated film has been prepared, an additional layer of film may be applied to cover, protect and seal the printed, coated, or decorated surface.

A schematic depiction of an exemplary film is shown in Figure 1.

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Film Examples

Tables 1.1, 1.2, and 1.3 show exemplary ingredients for fabricating films of the invention.

10 Table 1.1

	Exemplary (%)	Preferred (%)	Example 1. (%)
Water soluble polymer	10-70	20-65	30
Tobacco	1-90	20-40	25
Flavor	1-40	5-15	10
Sweetener	0.2-6	2-5	3
Fiber (Soluble or insoluble)	2-40	5-20	9
Plasticizer	1-40	5-15	10
Surfactants	0.01-20	0.1-1	0.5
Starch/Maltodextrin	1-40	10-20	10.5
Lubricant	0.5-10	1-3	2

Table 1.2 Mint Film

Ingredient	Percentage (dry weight)
Klucel EF Hydroxypropylcellulose	23.97%
Tobacco	23.29%
Walocel HM100PA2208 Hydroxypropylmethylcellulose	12.00%
B700 Modified Food Starch	11.66%
Mint Flavor Oil	7.99%
Propylene Glycol	4.25%
Glycerin	3.73%
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	3.73%
Sodium Carbonate	2.32%
Natural Tobacco Enhancer 631536	2.13%
Walocel HM4000PA2910 Hydroxypropylmethylcellulose	2.01%
Sodium Chloride	0.75%
Ammonium Carbonate	0.56%
Sucralose (from Liquid Concentrate 25%)	0.53%
Grindsted Propylene Glycol Monostearate USV-K	0.53%
Sodium Lauryl Sulfate	0.53%

Table 1.3

Ingredient	Percentage (dry weight)
Klucel EF Hydroxypropylcellulose	23.97%
Tobacco	23.29%
Walocel HM100PA2208 Hydroxypropylmethylcellulose	12.00%
B700 Modified Food Starch	11.66%
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	5.33%
Cinnamon Flavor Oil	5.33%
Glycerin	4.80%
Propylene Glycol	4.25%
Sodium Carbonate	2.32%
Natural Tobacco Enhancer 631536	2.13%
Walocel HM4000PA2910 Hydroxypropylmethylcellulose	2.01%
Sodium Chloride	0.75%
Ammonium Carbonate	0.56%
Sucralose (from Liquid Concentrate 25%)	0.53%
Grindsted Propylene Glycol Monostearate USV-K	0.53%
Sodium Lauryl Sulfate	0.53%

Example 2. Tobacco Film

A mixture of 50 grams of K-3 (60%), K-100 (35%) and K4M (5%)
 grades of hydroxypropylmethyl cellulose (HPMC) from Dow Chemical are
 added to a beaker containing 450 grams of well agitated, deionized water
 which has been heated to 180°F. While mixing, 40 grams of finely ground
 tobacco are added to the HPMC solution along with 15 grams of
 microcrystalline cellulose (FMC), 17 grams of starch (B-700 from Grain
 Processing Corp.), 16 grams of glycerine, 0.8 grams of polysorbate 80
 (Unichema), and 4 grams of propylene glycol monostearate (PGMS from
 Danisco). Ten grams of cinnamon flavor and 2 grams of sucralose (artificial
 sweetener) are added to the solution when the temperature has dropped below
 100 °F. Two grams of sodium carbonate are added to adjust pH to
 approximately 7.5. Once all ingredients have been added and have been
 uniformly dispersed, the mixture is place in a water bath and, with continued
 mixing for 30 minutes, is reduced in temperature to 65 °F. Additional water is
 added as required to obtain a Brookfield viscosity of 5,000 centipoise at a
 temperature of 65 °F, resulting in solution solids of approximately 17% w/w.

A portion of this tobacco containing solution described above is then spread on a glass plate using a draw down blade with a fixed gap of 15 mils (0.015 inches). The glass plate is placed in an air circulating laboratory oven preset at a temperature of 170 °F. After 30 minutes, the glass plate is removed
5 from the oven, cooled to room temperature, and the dry film with a thickness of 2.5 mils (0.0025 inches) is removed from the glass plate. The film may then be cut into smaller pieces suitable for placing in the mouth. A 1.0 inch by 1.25 inch section of the film will typically disintegrate in the mouth in less than one minute, thereby releasing the flavor, sweetener, and tobacco. The tobacco
10 content of this film on a dry weight basis is 25%.

Example 3. Opaque, Flavored Film

Using the same procedure as Example 2, a solution is prepared without the addition of tobacco. While the solution is still hot, 32 grams of a titanium
15 dioxide dispersion (50% titanium dioxide in water) supplied by Sensient Colors and 0.01 grams of FD&C Red No. 40 lake (Sensient Colors) are added with agitation. The solution is cooled to 65°F and is spread on a glass plate, dried, and removed from the glass plate as described in Example 2. An opaque, light red film of good strength and a dry film thickness of 15 mils (0.015 inches) is
20 produced.

Example 4. Two Layer Film

A portion of the solution from Example 2 is spread on a glass plate using a draw down blade with a fixed gap of 15 mils (0.015 inches). The glass
25 plate is placed in a laboratory oven, and the film is dried as in Example 2. The glass plate is removed from the oven and cooled to room temperature, but the film is not removed from the glass plate.

A portion of the solution from Example 3 is spread over the dry film of Example 2 using a draw down blade with a fixed gap of 5 mils (0.005 inches).
30 The glass plate is placed in the laboratory oven at 170°F for 10 minutes. The

dry film with a thickness of 3 mils (0.003 inches) is removed from the glass plate. The film is distinctly two sided with a layer of brown, tobacco containing film on one side and a red, flavored film on the opposite side. A 1.0 inch by 1.25 inch section of the film will typically disintegrate in the mouth in
5 less than one minute.

Example 5. Three Layer Film

A portion of the solution from Example 3 is spread on a glass plate using a draw down blade with a fixed gap of 5 mils and is dried in the
10 laboratory oven as before. A portion of the solution from Example 2 is spread over the dried film of Example 3 using a draw down blade with a fixed gap of 15 mils and is dried in the laboratory oven as before. A portion of the solution from Example 3 is spread on a glass plate using a draw down blade with a fixed gap of 5 mils and is dried in the laboratory oven as before. The resulting film
15 is 3 mils (0.003 inches) in thickness and is comprised of three layers with a layer of opaque, red, flavored film on either side and a center layer of tobacco containing film. A 1.0 inch by 1.25 inch section of the film will typically disintegrate in the mouth in less than one minute.

20 Example 6. Foamed Film

To a 100 gram portion of tobacco containing solution from Example 2 is added with vigorous mixing, 0.5 grams of sodium lauryl sulfate (a surface active agent). This solution is then mixed on a high shear mixer such as a Silverson Laboratory Homogenizer, Model L4RT-W, to create a uniform
25 bubble structure. This highly aerated solution is then spread on a glass plate using a draw down blade with a fixed gap of 40 mils (0.040 inches) and is dried in a laboratory oven. The dry, foamed film has a thickness of 4 mils (0.004 inches) when it is removed from the glass plate. The weight of a section of this foamed film of 1.0 inch by 1.25 inch by 4 mils (0.004 inches) in thickness is

35% lower than an identical section of unfoamed film as prepared in Example 2. The disintegration rate of the foamed film in the mouth is typically faster when compared to the identical unfoamed film as prepared in Example 2.

5 Example 7. Flakes

A solution is prepared in a beaker by adding 40 grams of spray dried Gum Arabic (TIC Gums, Inc.) and 0.4 grams of propylene glycol monostearate (PGMS) to 60 grams deionized water while mixing vigorously for 30 minutes. To 10 grams of this solution, 0.01 grams of FD&C Red No. 40 lake is added
10 with high agitation to ensure uniform dispersion of the color. The solution is covered and set aside for 24 hours to permit all entrapped air to dissipate. A portion of this solution is then spread on a glass plate using a draw down blade with a fixed gap of 5 mils (0.005 inches). The glass plate is placed in a laboratory oven preset at 170 °F for 20 minutes until the film is thoroughly
15 dried. When the film is removed from the glass plate, it breaks into many small pieces of high gloss, colorful, red flakes. This process is repeated with other FD&C lakes to produce flakes of many different colors. Flavors and artificial sweeteners can also be added to the flakes.

20 Example 8. Tobacco Flakes

To 10 grams of the solution prepared in Example 7 is added 4 grams of finely ground tobacco powder. Films are prepared on glass plates and are dried, cooled, and removed in the same manner as in Example 7. The resulting flakes are composed of 50% tobacco and 50% Gum Arabic and are a deep
25 brown color. Flavors, if desired, can be added to the flakes. Materials such as sodium carbonate can also be added to the flakes to adjust pH.

Example 9. Tobacco Film with Flakes

A film is prepared as in Example 2. While the film is still wet on the
30 glass plate, a measured quantity of flakes are prepared as in Example 8 and are

spread uniformly over the wet film. The glass plate is then dried in a laboratory oven; the film is cooled to room temperature and then removed from the glass plate. Typically, the dried film of Example 2 has a dry weight of 1 gram (containing 25% or 0.25 grams of tobacco). If this film is divided into 20 equal sections of film (1.0 inch by 1.25 inches by 2 mils), each section will weigh 50 milligrams (containing 25% or 12.5 milligrams of tobacco). If one gram of tobacco flakes (which are 50% by weight of tobacco) are spread uniformly over the film, the full piece of film will have a dry weight of 2 grams (containing a total of 0.75 grams of tobacco). When divided into 20 equal sections, each section will weigh 100 milligrams and will contain 37.5 milligrams of tobacco. The section of film cut into a 1.0 inch by 1.25 inch size will typically disintegrate in the mouth in less than one minute.

Example 10. Tobacco Film with Decorative Flakes

The procedure outlined in Example 9 can be repeated using decorative flakes (e.g., colored flakes which do not contain any tobacco) or with blends of colored flakes and tobacco containing flakes. The resulting films have a colorful appearance.

Example 11. Flavored Tobacco Film

Table 11.1

HPMC/HPC	36.56%
Starch	12.18%
Tobacco	24.37%
Na ₂ CO ₃	1.46%
Plasticizer	13.15%
Flavors	6.82%
Sweetener	0.49%
Surfactant	0.97%
Water	4.00%

The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	Klucel EF (Hercules)	30.98g
	HM100PA2208(Wolff Cellulosics)	15.51g
5	HM4000PA2910(Wolff Cellulosics)	2.60g
	B-792(Grain Processing Corporation)	16.36g
	Tobacco Powder (average particle size <80 µm)	32.72g

The resultant mixture was mixed until homogeneous. In a separate
 10 container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	1.96g
	Propylene Glycol Monostearate	0.65g
15	Sodium Lauryl Sulfate	0.65g

In a third container were weighed the following ingredients:

	MIX3	
20	Glycerin	5.89g
	Propylene Glycol	5.22g
	Polyethylene Glycol 400	6.54g
	Cinnamon Flavor	6.54g
	Tobacco Flavor Modifier (Hagelin)	2.62g
25	Sucralose Solution 25% (Tate & Lyle)	2.62g

A total of 619.14g of boiling water was weighed into a stainless steel
 container. The water was stirred vigorously with an Arrow Model 1750 high
 shear mixer. To the water was added MIX2. Stirring was continued for 30
 30 seconds, at which point MIX1 was added. Vigorous stirring was continued for
 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was
 continued for 1 minute. The resultant solution was transferred to a Silverson
 SS1 vessel, which had been adapted for mixing under vacuum. The vessel was
 attached to a Silverson L4RTU homogenizer motor unit. The solution was
 35 homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM,
 after which an ice bath was placed around the homogenizer vessel.

Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10,000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

5 A portion of the resultant gel solution was poured onto a glass plate that had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 15 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 30 minutes, which had been set at 75°C. The resultant film, dried to approximately 4% moisture, was removed from the
10 Mylar sheet and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film disintegrated in the mouth in less than 30 seconds.

Relatively slower disintegrating films (e.g., films disintegrating in the mouth in greater than 30 seconds) were produced from the same solutions by casting the solution across the glass plate with a draw-down knife with a fixed
15 gap of 30 mils. The films were dried in the same manner as above for 40 minutes. The films produced typically disintegrated in the mouth in less than 1 minute.

Super-fast disintegrating films (e.g., films disintegrating in the mouth in less than 15 seconds) were produced from the same solutions by foaming the
20 solution prior to casting on the glass plate. Foaming was accomplished by subjecting 100g of each solution to high shear mixing (with an Arrow Model 1750 high shear mixer) for approximately 3 minutes, after which the foamed solution was immediately cast on the glass plate with a draw-down knife with a fixed gap of 30 mils. The films produced typically disintegrated in the mouth
25 in less than 15 seconds.

Example 12. Flavored Tobacco Film

Table 12.1

HPMC	36.56%
Starch	12.18%
Tobacco	24.37%
Na ₂ CO ₃	1.46%
Plasticizer	10.71%
Flavors	9.26%
Sweetener	0.49%
Surfactant	0.97%
Water	4.00%

- 5 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM3PA2910 (Wolff Cellulosics)	30.98g
10	HM100PA2208 (Wolff Cellulosics)	15.51g
	HM4000PA2910 (Wolff Cellulosics)	2.60g
	B700 (Grain Processing Corporation)	16.36g
	Tobacco Powder (avg. particle size <80 μ m)	32.72g

- 15 The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	1.96g
	Propylene Glycol Monostearate	0.65g
20	Sodium Lauryl Sulfate	0.65g

In a third container were weighed the following ingredients:

	MIX3	
25	Glycerin	4.58g
	Propylene Glycol	5.22g
	Polyethylene Glycol 400	4.58g
	Mint Flavor	9.81g
	Tobacco Flavor Modifier (Hagelin)	2.62g
30	Sucralose Solution 25% (Tate & Lyle)	2.62g

A total of 619.14g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point MIX1 was added. Vigorous stirring was continued for 5 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 1 minute. The resultant solution was transferred to a Silverson SS1 vessel, which had been adapted for mixing under vacuum. The vessel was attached to a Silverson L4RTU homogenizer motor unit. The solution was homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM, 10 after which an ice bath was placed around the homogenizer vessel. Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

A portion of the resultant gel solution was poured onto a glass plate that 15 had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 15 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 30 minutes, which had been set at 75°C. The resultant film, dried to approximately 4% moisture, was removed from the 20 Mylar sheet and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film typically disintegrated in the mouth in 15-30 seconds.

Alternatively, the film includes wintergreen, spearmint, or apple flavor.

Relatively slower disintegrating films (e.g., films disintegrating in the mouth in greater than 30 seconds) and super-fast disintegrating films (e.g., 25 films disintegrating in the mouth in less than 15 seconds) were produced from the same solutions as described in Example 11.

Example 13. Peach Flavored Tobacco Film

Table 13.1

HPMC	29.12%
Starch	9.71%
Tobacco	19.41%
Na ₂ CO ₃	1.16%
Plasticizer	2.33%
Peach Puree	29.66%
Flavors	3.43%
Sweetener	0.39%
Surfactant	0.77%
Water	4.00%

- 5 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM3PA2910 (Wolff Cellulosics)	30.98g
10	HM100PA2208 (Wolff Cellulosics)	15.51g
	HM4000PA2910 (Wolff Cellulosics)	2.60g
	B700 (Grain Processing Corporation)	16.36g
	Tobacco Powder (average particle size <80 µm)	32.72g

- 15 The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	1.96g
20	Propylene Glycol Monostearate	0.65g
	Sodium Lauryl Sulfate	0.65g

In a third container were weighed the following ingredients:

25	MIX3	
	Glycerin	1.31g
	Propylene Glycol	1.31g
	Polyethylene Glycol 400	1.31g
	Peach Puree	100.0g
30	Peach Flavor	3.27g
	Tobacco Flavor Modifier (Hagelin)	2.62g
	Sucralose Solution 25% (Tate & Lyle)	2.62g

A total of 619.14g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point MIX1 was added. Vigorous stirring was continued for 5 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 1 minute. The resultant solution was transferred to a Silverson SS1 vessel, which had been adapted for mixing under vacuum. The vessel was attached to a Silverson L4RTU homogenizer motor unit. The solution was homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM, 10 after which an ice bath was placed around the homogenizer vessel. Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

A portion of the resultant gel solution was poured onto a glass plate 15 which had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 15 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 30 minutes, which had been set at 75°C. The resultant film, dried to approximately 4% moisture, was removed from the 20 Mylar sheet, and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film typically disintegrated in the mouth in 15-30 seconds.

Relatively slower disintegrating films (e.g., films disintegrating in the mouth in greater than 30 seconds) and super-fast disintegrating films (e.g., films disintegrating in the mouth in less than 15 seconds) were produced from 25 the same solutions as described in Example 11.

Example 14. Flavored Tobacco Film for Sticks/Wraps/Pouches/Vacuum Forming

Table 14.1

HPMC	41.31%
Starch	13.76%
Tobacco	9.75%
Na ₂ CO ₃	1.46%
Plasticizer	18.99%
Flavors	9.27%
Sweetener	0.49%
Surfactant	0.98%
Water	4.00%

5

The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
10	HM3PA2910 (Wolff Cellulosics)	38.48g
	HM100PA2208 (Wolff Cellulosics)	19.27g
	HM4000PA2910 (Wolff Cellulosics)	3.24g
	B700 (Grain Processing Corporation)	20.32g
	Tobacco Powder (avg. particle size <80 µm)	14.39g

15

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
20	Na ₂ CO ₃	2.16g
	Propylene Glycol Monostearate	0.72g
	Sodium Lauryl Sulfate	0.72g

In a third container were weighed the following ingredients:

25

	MIX3	
	Glycerin	7.19g
	Propylene Glycol	7.19g
	Polyethylene Glycol 400	7.19g
30	Triacetin	6.47g
	Cinnamon Flavor	10.80g
	Tobacco Flavor Modifier (Hagelin)	2.88g
	Sucralose Solution 25% (Tate & Lyle)	2.88g

A total of 606.10g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30
5 seconds, at which point MIX1 was added. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 1 minute. The resultant solution was transferred to a Silverson SS1 vessel, which had been adapted for mixing under vacuum. The vessel was attached to a Silverson L4RTU homogenizer motor unit. The solution was
10 homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM, after which an ice bath was placed around the homogenizer vessel. Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

15 A portion of the resultant gel solution was poured onto a glass plate which had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The
20 resultant film, dried to approximately 4% moisture, was removed from the Mylar sheet, and was stored in a plastic bag for future use.

Alternatively flavored tobacco films, e.g., apple flavored, were also produced following the preceding formulation and procedure.

Example 15. Flavored/Colored Film for Sticks/Wraps/Pouches

Table 15.1

HPMC	41.31%
Starch	13.76%
Fibersol-2	9.75%
Na ₂ CO ₃	1.46%
Plasticizer	18.99%
Flavors	9.26%
Sweetener	0.49%
Surfactant	0.79%
Color	0.20%
Water	4.00%

5 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM3PA2910 (Wolff Cellulosics)	38.48g
10	HM100PA2208 (Wolff Cellulosics)	19.27g
	HM4000PA2910 (Wolff Cellulosics)	3.24g
	B700 (Grain Processing Corporation)	20.32g
	Fibersol-2 (Matsutani)	14.39g
15	FD&C Red 40 Alum Lake 35-42% (Sensient Colors)	0.29g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	2.16g
20	Propylene Glycol Monostearate	0.58g
	Sodium Lauryl Sulfate	0.58g

In a third container were weighed the following ingredients:

25	MIX3	
	Glycerin	7.19g
	Propylene Glycol	7.19g
	Polyethylene Glycol 400	7.19g
	Triacetin	6.47g
30	Cinnamon Flavor	10.79g
	Tobacco Flavor Modifier (Hagelin)	2.88g
	Sucralose Solution 25% (Tate & Lyle)	2.88g

Example 16. White-Paper Like Film for Sticks/Wraps/Pouches

Table 16.1

HPC	26.33%
HPMC	15.41%
Insoluble Fiber	38.52%
Na ₂ CO ₃	1.48%
Plasticizer	4.93%
Flavors	7.39%
Sweetener	0.48%
Surfactant	0.48%
TiO ₂	0.98%
Water	4.00%

5

MIX 1

Klucel EF (Hercules)	20.53g
HM100PA2208 (Wolff Cellulosics)	10.28g
HM400PA2910 (Wolff Cellulosics)	1.73g
Solkafloc 200 FCC (International Fiber)	30.03g

10

MIX 2

Na ₂ CO ₃	1.15g
Propylene Glycol Monostearate	0.38g

15

MIX 3

Glycerin	0.96g
Propylene Glycol	0.96g
Polyethylene Glycol 400	0.96g
Mint Flavor	5.76g
Sucralose Solution 25%	1.54g
TiO ₂ 50% Dispersion	1.54g

20

25 A total of 606.10g of boiling water was weighed into a stainless steel
 container. The water was stirred vigorously with an Arrow Model 1750 high
 shear mixer. To the water was added MIX2. Stirring was continued for 30
 seconds, at which point was added MIX1. Vigorous stirring was continued for
 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was
 continued for 1 minute. The resultant solution was transferred to a Silverson
 30 SS1 vessel, which had been adapted for mixing under vacuum. The vessel was

attached to a Silverson L4RTU homogenizer motor unit. The solution was homogenized under vacuum (20-25 inches) for 2 minutes at 7500 RPM, after which an ice bath was placed around the homogenizer vessel. Homogenization continued under vacuum (20-25 inches) for 8 minutes at 10000 RPM. After
 5 homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

A portion of the resultant gel solution was poured onto a glass plate that had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a
 10 fixed gap of 20 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. Additional films were cast at 40 mils, and dried for 1 hour. The resultant films dried to approximately 4% moisture, were removed from the Mylar sheet, and were stored in a plastic bag for future use.

15 Alternative flavors include mint flavor, wintergreen flavor, or spearmint flavor. Alternative colors include FD&C Blue Alum Lake 35-42%, FD&C Emerald Green Lake Blend, and FD&C Blue Alum Lake + FD&C Emerald Green Lake Blend.

20 Example 17. Peach Flavored Film for Sticks/Wraps/Pouches

Table 17.1

HPMC	31.73%
Starch	10.57%
Tobacco	7.49%
Na ₂ CO ₃	1.12%
Plasticizer	14.59%
Peach Puree	26.01%
Flavors	3.37%
Sweetener	0.37%
Surfactant	0.75%
Water	4.00%

The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
5	HM3PA2910 (Wolff Cellulosics)	38.48g
	HM100PA2208 (Wolff Cellulosics)	19.27g
	HM4000PA2910 (Wolff Cellulosics)	3.24g
	B700 (Grain Processing Corporation)	20.32g
10	Tobacco Powder (average particle size <80 μ m)	14.39g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
15	Na ₂ CO ₃	2.16g
	Propylene Glycol Monostearate	0.72g
	Sodium Lauryl Sulfate	0.72g

In a third container were weighed the following ingredients:

	MIX3	
	Glycerin	7.19g
	Propylene Glycol	7.19g
	Polyethylene Glycol 400	7.19g
25	Triacetin	6.47g
	Peach Puree	100.0g
	Peach Flavor	3.60g
	Tobacco Flavor Modifier (Hagelin)	2.88g
30	Sucralose Solution 25% (Tate & Lyle)	2.88g

A total of 606.10g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point was added MIX1. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 1 minute. The resultant solution was transferred to a Silverson SS1 vessel, which had been adapted for mixing under vacuum. The vessel was attached to a Silverson L4RTU homogenizer motor unit. The solution was homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM,

after which an ice bath was placed around the homogenizer vessel.

Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

- 5 A portion of the resultant gel solution was poured onto a glass plate that had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The
- 10 resultant film, dried to approximately 4% moisture, was removed from the Mylar sheet, and was stored in a plastic bag for future use.

Example 18. Flavored/White Opaque Film for Coating

15

Table 18.1

HPMC	45.46%
Starch	15.15%
Fibersol-2	10.73%
Na ₂ CO ₃	1.07%
Plasticizer	10.73%
TiO ₂	10.45%
Flavors	1.07%
Sweetener	0.27%
Surfactant	1.07%
Water	4.00%

The following ingredients were weighed and combined in a container of suitable volume:

20	MIX1	
	HM3PA2910 (Wolff Cellulosics)	38.48g
	HM100PA2208 (Wolff Cellulosics)	19.27g
	HM4000PA2910 (Wolff Cellulosics)	3.24g
	B700 (Grain Processing Corporation)	20.32g
25	Fibersol-2 (Matsutani)	14.39g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

5	MIX2	
	Na ₂ CO ₃	1.44g
	Propylene Glycol Monostearate	0.72g
	Sodium Lauryl Sulfate	0.72g

10 In a third container were weighed the following ingredients:

	MIX3	
	Glycerin	3.60g
	Propylene Glycol	3.60g
	Polyethylene Glycol 400	3.60g
15	Triacetin	3.60g
	TiO ₂ suspension 50% (Sensient Colors)	28.04g
	Tobacco Flavor Modifier (Hagelin)	1.44g
	Sucralose Solution 25% (Tate & Lyle)	1.44g

20 A total of 606.10g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point was added MIX1. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was

25 continued for 1 minute. The resultant solution was transferred to a Silverson SS1 vessel, which had been adapted for mixing under vacuum. The vessel was attached to a Silverson L4RTU homogenizer motor unit. The solution was homogenized under vacuum (20-25 inches of Hg) for 2 minutes at 7500 RPM, after which an ice bath was placed around the homogenizer vessel.

30 Homogenization continued under vacuum (20-25 inches of Hg) for 8 minutes at 10000 RPM. After homogenization was complete, a portion of the solution was transferred to a 500-mL Nalgene bottle for storage.

A portion of the resultant gel solution was poured onto a glass plate which had previously been covered with an appropriately sized sheet of Mylar.

35 The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air

oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The resultant film, dried to approximately 4% moisture, was removed from the Mylar sheet, and was stored in a plastic bag for future use.

5 Example 19. Extruded Tobacco Films

Table 19.1

Tobacco	25.63%
Klucel LF	61.53%
Na ₂ CO ₃	3.32%
Plasticizer	6.68%
Sweetener	0.83%
Water	2.00%

The following ingredients were granulated in a manner similar to
 10 granulations utilized for tab production, as described herein, yielding a tobacco granulation with an approximate moisture of 4.50%:

	Klucel LF (Hercules)	3448.0g
	Na ₂ CO ₃	181.0g
15	Sucralose (Tate & Lyle)	45.0g
	Propylene Glycol	363.0g
	Tobacco Powder (average particle size <80 µm)	1451.0g
	Water	2344.0g

20 The tobacco granulation was introduced to the feed section of a Leistritz Micro-18 Twin Screw Extruder 40:1 L/D, which had been configured for co-rotating extrusion with a medium-shear screw design. Feed rates for the extrusion varied between 1 – 3 pounds per hour. Barrel zone temperatures varied between 75 – 240 °F. Venting of volatiles from the extrusion melt was
 25 accomplished by incorporating a venting orifice prior to the discharge die of the extruder.

Tobacco film, with a width of approximately 3 inches and a thickness varying from 2 – 3 mils, was produced by incorporating a strip die at the discharge end of the extruder. Upon discharge, the tobacco film was
 30 calendared and cooled to room temperature by utilizing a 3-roll stacked chill

roller. Downstream from the chill roller the film was taken up on a rewind reel, incorporating Mylar between the film layers to prevent adhesion. The tobacco film was placed in a container suitable for storage.

The tobacco film was subsequently used in the manufacture of
 5 disintegrable tobacco containing pouches, as described herein. The film disintegrated slowly in the mouth, over a period of 2 – 4 minutes.

Example 20. Flavored Tobacco Film with Gelatin

10

Table 20.1

HPMC	35.95%
Gelatin	0.98%
Starch	12.30%
Tobacco	23.64%
Na ₂ CO ₃	1.47%
Plasticizer	10.84%
Flavors	9.35%
Sweetener	0.50%
Surfactant	0.97%
Water	4.00%

The following ingredients were weighed and combined in a container of suitable volume:

15	MIX1	
	HM3PA2910 (Wolff Cellulosics)	13.84g
	HM100PA2208 (Wolff Cellulosics)	7.24g
	HM4000PA2910 (Wolff Cellulosics)	1.21g
	B700 (Grain Processing Corporation)	7.63g
20	Gelatin	0.61g
	Tobacco Powder (average particle size <80 µm)	15.27g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

25	MIX2	
	Na ₂ CO ₃	0.91g
	Propylene Glycol Monostearate	0.30g
30	Sodium Lauryl Sulfate	0.30g

In a third container were weighed the following ingredients:

	MIX3	
	Glycerin	2.14g
5	Propylene Glycol	2.44g
	Polyethylene Glycol 400	2.14g
	Mint Flavor	4.58g
	Tobacco Flavor Modifier (Hagelin)	1.22g
10	Sucralose Solution 25% (Tate & Lyle)	1.22g

A total of 288.93g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point was added MIX1. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 3 minutes. The resultant solution was transferred to a suitable container for storage.

A portion of the resultant gel solution was poured onto a glass plate which had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The resultant film dried to approximately 4% moisture, was removed from the Mylar sheet, and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film disintegrated in the mouth in less than 30 seconds, releasing flavor, sweetener, and tobacco.

Example 21. Flavored Tobacco Film with Gelatin

Table 21.1

HPMC	32.01%
Gelatin	4.92%
Starch	12.30%
Tobacco	23.64%
Na ₂ CO ₃	1.47%
Plasticizer	10.84%
Flavors	9.35%
Sweetener	0.50%
Surfactant	0.97%
Water	4.00%

5 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM3PA2910 (Wolff Cellulosics)	11.40g
10	HM100PA2208 (Wolff Cellulosics)	7.24g
	HM4000PA2910 (Wolff Cellulosics)	1.21g
	B700 (Grain Processing Corporation)	7.63g
	Gelatin	3.05g
15	Tobacco Powder (average particle size <80 µm)	15.27g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	0.91g
20	Propylene Glycol Monostearate	0.30g
	Sodium Lauryl Sulfate	0.30g

In a third container were weighed the following ingredients:

25	MIX3	
	Glycerin	2.14g
	Propylene Glycol	2.44g
	Polyethylene Glycol 400	2.14g
	Mint Flavor	4.58g
30	Tobacco Flavor Modifier (Hagelin)	1.22g
	Sucralose Solution 25% (Tate & Lyle)	1.22g

A total of 288.93g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point was added MIX1. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 3 minutes. The resultant solution was transferred to a suitable container for storage.

A portion of the resultant gel solution was poured onto a glass plate which had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The resultant film dried to approximately 4% moisture, was removed from the Mylar sheet, and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film disintegrated in the mouth in less than 30 seconds, releasing flavor, sweetener, and tobacco.

Example 22. Flavored Tobacco Film with Gelatin

Table 22.1

HPMC	27.09%
Gelatin	9.85%
Starch	12.30%
Tobacco	23.64%
Na ₂ CO ₃	1.47%
Plasticizer	10.84%
Flavors	9.35%
Sweetener	0.50%
Surfactant	0.97%
Water	4.00%

The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM3PA2910 (Wolff Cellulosics)	8.35g
	HM100PA2208 (Wolff Cellulosics)	7.24g
5	HM4000PA2910 (Wolff Cellulosics)	1.21g
	B700 (Grain Processing Corporation)	7.63g
	Gelatin	6.11g
	Tobacco Powder (average particle size <80 µm)	15.27g

10 The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
	Na ₂ CO ₃	0.91g
15	Propylene Glycol Monostearate	0.30g
	Sodium Lauryl Sulfate	0.30g

In a third container were weighed the following ingredients:

20	MIX3	
	Glycerin	2.14g
	Propylene Glycol	2.44g
	Polyethylene Glycol 400	2.14g
	Mint Flavor	4.58g
25	Tobacco Flavor Modifier (Hagelin)	1.22g
	Sucralose Solution 25% (Tate & Lyle)	1.22g

A total of 288.93g of boiling water was weighed into a stainless steel container. The water was stirred vigorously with an Arrow Model 1750 high shear mixer. To the water was added MIX2. Stirring was continued for 30 seconds, at which point was added MIX1. Vigorous stirring was continued for 4 minutes. To the resultant solution was added MIX3. Vigorous stirring was continued for 3 minutes. The resultant solution was transferred to a suitable container for storage.

35 A portion of the resultant gel solution was poured onto a glass plate which had previously been covered with an appropriately sized sheet of Mylar. The gel solution was drawn across the glass plate with a draw-down knife with a fixed gap of 20 mils. The glass plate was placed in a side-swept forced air

oven (VWR model 1330FM), for 35 minutes, which had been set at 75°C. The resultant film dried to approximately 4% moisture, was removed from the Mylar sheet, and cut into appropriately sized units. A 1.0 inch by 1.25 inch unit of film disintegrated in the mouth in less than 30 seconds, releasing flavor, sweetener, and tobacco.

Tabs. Compositions of the invention may also be produced as tabs, such as super fast disintegrate (about 15 seconds), fast disintegrate (less than 2 minutes), slow disintegrate (2-10 minutes), chewable tabs, and effervescent tabs. Exemplary tabs are shown in Figures 2A-2B, 3A-3B, and 4A-4B.

Tabs may be sized as individual servings or smaller, a plurality of which constitute an individual serving. Tabs sized as individual servings typically have dimensions of 5 mm to 15 mm. Smaller tabs typically range from 2 to 4 mm in diameter. Such smaller tabs may be fabricated in a variety of colors or flavors, e.g., for simultaneous consumption. Tabs may be shaped as a wafer, a convex or concave pellet, ovals, or any other shape known to the trade. Tabs may also be foamed to provide faster dissolution or disintegration in the mouth. Tabs may also be layered to provide a variety of tastes or mouth feels as the tab dissolves or disintegrates. Tabs may also be coated to modify color or taste or to provide mechanical strength for improved handling. In one embodiment, a tab designed to disintegrate rapidly in water may be coated with a very thin water insoluble coating to provide protection to the tab while a second, water soluble coating is applied.

Tabs may be fabricated from a dry mix, known as direct compression or from pregranulated materials by any forming method known in the art, e.g., via a press, injection molding, compression molding, injection foam molding, or compression foam molding.

Tab Examples

Tables 23.1, 23.2, and 23.3 show exemplary ingredients for fabricating tabs of the invention.

5 Table 23.1

	Exemplary Range (%)	Example 23 Fast (%)	Example 24 Fast (%)	Example 25 low (%)	Example 26. Slow (%)
Water soluble polymer	0-70	0	3	23	0
Tobacco	1-70	27	20	27	30
Flavor Oil	0.5-4.0	2	1.8	2	2
Artificial Sweetener	0.05-0.4	0.15	0.15	0.15	0.1
Sugar	1-80	64	35	45.85	33.3
Maltodextrin	0-50	0	19	0	0
Disintegrant	0.1-15	6.35	3.0	-	-
Starch	5-80	0	17.35	-	50
Release Agent	0.1-2.0	0.5	0.5	0.5	0.5
Emulsifier	0.1-5.0	0	0.2	0.5	0.1

Table 23.2 Mint Tab

Ingredient	Percentage (dry weight)
Maltodextrin M585	38.87%
Mannogem TM 2080 Granular USP/FCC	32.81%
Tobacco	23.85%
Magnesium Stearate Food Grade NF Kosher	1.02%
Sodium Chloride	0.77%
Sodium Carbonate	0.74%
Mint Flavor Oil	0.62%
Ammonium Carbonate	0.58%
Gum Arabic Prehydrated FT	0.49%
Spearmint Flavor Oil	0.15%
Sucralose	0.11%

Table 23.3 Cinnamon Tab

Ingredient	Percentage (dry weight)
Maltodextrin M585	41.20%
Lactose Refined Edible	29.48%
Tobacco	24.03%
Gum Arabic Prehydrated FT	1.26%
Magnesium Stearate Food Grade NF Kosher	1.03%
Cinnamon Flavor Oil	0.78%
Sodium Chloride	0.78%
Sodium Carbonate	0.74%
Ammonium Carbonate	0.58%
Sucralose	0.12%

Example 27. Exemplary Chewable Tab

A chewable tab can be formed using the following ingredients:
compressible sugar (30-50%, e.g., 40%); tobacco (10-30%, e.g., 20%);
dextrose (15-40%, e.g., 25); maltodextrin (5-20%, e.g., 13%); coloring agents
5 (0.01-0.10%, e.g., 0.05%); flavor (0.5-2%, e.g., 1.35%); magnesium stearate
(0.10-2%, e.g., 0.60%).

Example 28. Exemplary Effervescent Tab

An effervescent tab can be formed using the ingredients of Example 27
10 with the addition of appropriate amounts of sodium bicarbonate and citric acid.
An exemplary effervescent tab is shown in Figures 4A-4B.

Example 29. Thermoplastic Tab

A thermoplastic tab can be formed using the following ingredients (in
15 parts): hydroxypropyl cellulose (HPC) 54; tobacco 27; microcrystalline
cellulose 10; propylene glycol 4; artificial sweetener 2; flavor 2; and stabilizer
0.2. The ingredients are dry mixed and fed to an extruder using barrel
temperatures necessary to melt the HPC (typically 340-370 °F). A rod of about
½ inch diameter is extruded and cut to size sufficient to form a tab.

20

Example 30. Tobacco Tab

Table 30.1. Formulation of Tobacco Tab

Ingredients	% Dry Weight Basis
Tobacco Powder	25.00
Sweetener	32.11
Maltodextrin	40.22
Flavors	0.75
Emulsifier	1.36
Na ₂ CO ₃	0.56
Total	100.00

Table 30.2. Formulation of Binding Solution for Production of Tobacco Tab

Ingredients	Per Cent
Water	45.00
Maltodextrin	53.05
Emulsifier	1.80
Sweetener	0.15
Total	100.00

Preparation of Binding Solution

Ingredient amounts, as noted in Table 30.2, were weighed out into
 5 separate containers. Gum Arabic Pre-hydrated (emulsifier) was slowly added
 to the water and mixed under high shear agitation in a stainless steel vessel.
 After complete dissolution, M 585 maltodextrin (Grain Processing
 Corporation) was added slowly to the water. Once M 585 was completely
 dissolved, the sucralose sweetener (Tate & Lyle) was added slowly and mixed
 10 thoroughly to ensure complete dissolution.

Formulary amounts of peppermint and spearmint flavors and Na_2CO_3 as
 noted in Table 30.1 were added to the binding solution. The entire mixture was
 homogenized for approximately 20 minutes at 9000-10000 RPM with the aid
 of a homogenizer. The proper amount of binding solution to use was
 15 determined by the batch size and the ingredient percentages shown in Table
 30.1. The homogenized solution was transferred into the flavor
 holding/pumping tank.

Preparation of Dry Ingredients

20 The formulary amounts of mannitol (sweetener) and tobacco powder, as
 noted in Table 30.1, were blended together and placed in the product bowl.

Preparation of Vector Multiflo-15 Fluid Bed Chamber

A Vector Multiflo-15 fluid bed coater was used to apply the binding
 25 solution to the dry ingredient blend to form the final granulation. The manual
 process was selected on the control panel computer. The machine operating
 parameters, located in Table 30.3, were loaded into the program:

Table 30.3. Vector Multiflo-15 Fluid Bed Parameter Settings

Parameters	Settings
Inlet Temperature (Celsius)	60
Airflow (CFM)	150
Flowrate (G/Min)	125
Filter Pulse Interval (Sec)	30
Post-Pulse Time (Sec)	60

5 The appropriate amount of binding solution to be sprayed on was also loaded into the program. The binding solution amount was determined by the desired batch size to achieve the ingredient percentages shown in Table 30.1.

Granulation Process

10 Once the dry ingredients were fluidized in the fluid bed chamber and reached a temperature of 40-45 °C, the binding solution was slowly sprayed onto the dry ingredients to form the granulation. The nozzle pressure was set at 22 psi and airflow at 200 CFM. The airflow was increased to ensure good product movement or fluidization in the fluid bed chamber. Once all the binding solution had been applied, the airflow was reduced to 200 CFM. The process was stopped once the product temperature reached approximately 43 °C.

Preparation of Granulation for Forming Tabs

20 The granulated material was then sized through a 12-mesh screen. The magnesium stearate (lubricant) was sized through a 40-mesh screen. The formulary amount of magnesium stearate as noted in Table 30.4 was combined with the granulated material in a plastic bag and manually shaken for 2 minutes.

Table 30.4. Formulation of Ingredients for Forming Tabs

Ingredients	% Dry Weight Basis
Granulated Material	99.50
Lubricant	0.50
Total	100.00

Tab Forming Process

5 The granulated material plus lubricant was loaded into the hopper of the press. The following parameters noted in Table 30.5 were set on the Vanguard VSP 8 Mini Rotary Press:

Table 30.5. Parameters for Tobacco Tab

Parameters	Fast Disintegrate		Slow Disintegrate	
	Settings	Ranges	Settings	Ranges
Fill Depth (mm)	8.0		11.3	11.3-11.4
Thickness (mm)	1.3		1.8	
Principal Pressure (kN)	5.0			10.8-12.0
Ejection Pressure (mm)				0.03-0.12

10 Fast disintegrate disintegrated in the mouth within 1 to 3 minutes. Slow disintegrate disintegrated in the mouth between 5-8 minutes.

Example 31. Tobacco Tab

15 Table 31.1. Formulation of Tobacco Tab

Ingredients	% Dry Weight Basis
Tobacco Powder	25.00
Sweetener	34.11
Maltodextrin	38.58
Flavors	1.00
Emulsifier	1.31
Total	100.00

Table 31.2. Formulation of Binding Solution for Production of Tobacco Tab

Ingredients	Per Cent
Water	45.00
Maltodextrin	53.04
Emulsifier	1.80
Sweetener	0.16
Total	100.00

The procedures stated in Example 30 for binding solution preparation were followed. Formulary amounts of peppermint and spearmint flavors as
 5 noted in Table 31.1 and 45.00 grams of Na_2CO_3 were added to binding solution. The remaining procedures for the make-up for the binding solution, preparation of dry ingredients, preparation of Vector Multiflo-15 Fluid Bed Chamber, and granulation process were followed.

10 Preparation of Granulation for Forming Tabs

The granulated material and magnesium stearate were sized through the appropriate screens as previously stated. The formulary amount of magnesium stearate (0.75% for a fast disintegrate or 1.00% for a slow disintegrate) was combined with the granulated material in a plastic bag and manually shaken for
 15 2 minutes.

Tab Forming Process

The machine operating parameters noted in Table 31.3 were set on the Vanguard VSP 8 Mini Rotary Press:

20

Table 31.3. Tab Forming Parameters for Tobacco Tab

Parameters	Fast Disintegrate		Slow Disintegrate	
	Settings	Ranges	Settings	Ranges
Fill Depth (mm)	6.8		9.9	
Thickness (mm)	1.1			2.0-2.1
Principal Pressure (kN)		6.9-7.2		3.8-4.0
Ejection Pressure (mm)				0.03-0.15

Example 32. Tobacco Tab

Table 32.1. Formulation of Tobacco Tab

Ingredients	% Dry Weight Basis
Tobacco Powder	25.00
Filler	30.00
Maltodextrin	42.15
Flavor	0.75
Emulsifier	1.43
Sweetener	0.12
Na ₂ CO ₃	0.56
Total	100

5 Table 32.2. Formulation of Binding Solution for Production of Tobacco Tab

Ingredients	Per Cent
Water	45.00
Maltodextrin	53.06
Emulsifier	1.80
Sweetener	0.14
Total	100.00

The procedures previously stated for binding solution preparation were followed. Formulary amounts of Cinnamon Flavor and Na₂CO₃ as noted in Table 32.1, were added to the binding solution. The remaining procedures for the make-up of the binding solution, preparation of dry ingredients (lactose filler combined with tobacco powder), preparation of the Vector Multiflo-15 Fluid Bed Chamber, and the granulation process were followed.

Preparation of Granulation for Forming Tabs

15 The granulated material and magnesium stearate were sized through 12- and 40 -mesh screens, respectively. The formulary amount of magnesium stearate (0.50% for a fast disintegrate or 1.00% for a slow disintegrate) was combined with the granulated material in a plastic bag and manually shaken for 2 minutes.

Tab Forming Process

The parameters noted in Table 32.3 were set on the Vanguard VSP 8 Mini Rotary Press:

5 Table 32.3. Tab Forming Parameters for Tobacco Tab

Parameters	Fast Disintegrate		Slow Disintegrate	
	Settings	Ranges	Settings	Ranges
Fill Depth (mm)	7.7		11.2	11.2-11.3
Thickness (mm)	1.1		1.7	1.7-1.8
Principal Pressure (kN)		5.7-6.0		3.8-4.0
Ejection Pressure (mm)		0.03-0.08		0.03-0.17

Example 33. Tobacco Tab

The same procedures were followed for making a Tobacco Tab in Example 32 except wintergreen flavor was used in place of cinnamon flavor.

10

Preparation of Granulation for Forming Tabs

The finished material was then sized through a 12-mesh screen. The magnesium stearate was sized through a 40-mesh screen. The formulary amount of magnesium stearate (0.50% for a fast disintegrate or 0.75% for a slow disintegrate) was combined with the granulated material in a plastic bag and manually shaken for 2 minutes.

15

Tab Forming Process for Tobacco Tab

The parameters noted in Table 33.1 were set on the Vanguard VSP 8 Mini Rotary Press:

20

Table 33.1. Tab Forming Parameters for Tobacco Tab

Parameters	Fast Disintegrate		Slow Disintegrate	
	Settings	Ranges	Settings	Ranges
Fill Depth (MM)	8.1		12.0	12.0-12.1
Thickness (MM)	1.1	1.1-1.2	1.8	
Principal Pressure (KN)	5.7	5.7-6.0	4.5	4.5-5.2
Ejection Pressure (MM)		0.03-0.09		0.04-0.19

Example 34. Tobacco Tab with an Opaque, White Coating

5 Table 34.1. Formulation of Tobacco Tab

Ingredients	% Dry Weight Basis
Tobacco	25.00
Filler	30.00
Maltodextrin	39.74
Flavor	0.75
Emulsifier	1.35
Sweetener	0.10
Na ₂ CO ₃	0.56
Tobacco Flavor Modifier	2.50
Total	100

Table 34.2. Formulation of Binding Solution for Production of Tobacco Tab

Ingredients	Per Cent
Water	45.00
Maltodextrin	53.07
Emulsifier	1.80
Sweetener	0.13
Total	100

Preparation of Binding Solution

10 The procedures previously stated for binding solution preparation were followed. Formulary amounts of apple flavor, natural bitter blocker (Comax), and Na₂CO₃ as noted in Table 34.1 were added to binding solution. The

remaining procedures for the make-up of the binding solution, preparation of dry ingredients (lactose filler plus tobacco powder), preparation of the Vector Multiflo-15 Fluid Bed Chamber, and the granulation process were followed.

5 Preparation of Granulation for Tab Forming

The finished material was then sized through a 12-mesh screen. The magnesium stearate was sized through a 40-mesh screen. The formulary amount of magnesium stearate (0.75% for a slow disintegrate) was combined with the granulated material in a plastic bag and manually shaken for 2
10 minutes.

Tab Forming Process

The parameters noted in Table 34.3 were set on the Vanguard VSP 8 Mini Rotary Press:

15

Table 34.3. Tab Forming Parameters for a Slow Disintegrate Tobacco Tab

Parameters	Settings	Ranges
Fill Depth (mm)	13.6	13.5-13.7
Thickness (mm)	2.4	2.4-2.5
Principal Pressure (kN)		4.5-5.2
Ejection Pressure (mm)		0.04-0.24

Tobacco Tab Coating-Suspension Makeup

A 20% Opadry II aqueous solution was prepared as directed by the
20 manufacturer and allowed to mix 45 minutes prior to coating.

Coating Process

Tabs (5.5-6.5 kG) were placed in the coating pan of a Vector/Freund Hi-Coater pan coating machine and warmed until the exhaust temperature reached
25 45 °C. This was done with the pan running at less than 5 RPM to minimize tab attrition. Air at 75 °C and 100 CFM ran across the pan at a pan pressure of – 0.5" water.

Once the tabs reached the desired temperature, the pan speed was increased to approximately 15 RPM and the Opadry coating suspension was applied at a rate of 15-20 grams/minute. The suspension was continually mixed during application to prevent the solids from settling. The spray was atomized with approximately 100 liters of air per minute at approximately 70 psi. The atomized spray was formed into a pattern using directional air ports on the nozzle set at approximately 50 liters of air per minute at approximately 70 psi.

Inlet air temperature was periodically increased or decreased to maintain an exhaust temperature between 43 and 46 °C.

Spraying was continued until desired amount of solids was applied to satisfy formulary requirements, typically around 3%, or until tabs were visually satisfactory.

Example 35. Multilayer Tab

Commercially available press equipment can be used to prepare tabs with two or more distinct layers. The composition of these layers can be the same or different. Individual layers can be differentiated by color, flavor, tobacco type, tobacco content, dissolution or disintegration rate, and other similar characteristics. For example, one layer could disintegrate very rapidly to release flavor or flavor masking ingredients. A second layer containing tobacco powder could disintegrate more slowly, thereby gradually exposing the tobacco. Exemplary multilayer tabs are shown in Figures 5A-5B and 6A-6B.

Example 36. Three Layer Tab

A multilayer tab, as described in Example 35, can be prepared with three layers: (1) a soft, breath freshening core, (2) a layer of polymer/tobacco enclosing the core; and (3) a fast disintegrating, tobacco containing coating on the outside. The soft core (1), a gel containing no tobacco but breath freshening flavors, is prepared. A molten mixture (2) containing an edible

polymer, water, tobacco (e.g., about 25% by weight), flavor and sweetener, at a pH of about 7.8 is prepared. This mixture is deposited in a mold on a Depositer. Before the mold is completely filled, a core (1) of the breath freshening gel is deposited in the center of the part. The mold is then filled
 5 with (2) and cooled. After cooling, the composition is removed from the mold and then coated with a thin coating of a polymer solution (3) containing, e.g., about 40% tobacco by weight, a pH of about 8.5, flavor, and sweetener.

When the composition is placed in the mouth of a user, the first layer disintegrates rapidly (30-60 seconds), providing flavor and tobacco satisfaction.
 10 The second, middle layer disintegrates more slowly (more than 5 minutes). Next the inner core is exposed, providing breath freshening flavors to the user.

Example 37. Tobacco Solid Disintegrable

15 The following ingredients were weighed out into individual containers:

	Klucel EF (Hercules)	60 g
	Tobacco Powder	75 g
	Tobacco Flavor Modifier	6 g
	Corn Syrup (65 %)	45 g
20	Sucrose	45 g
	B700 (Grain Processing Corp.)	51 g
	Sucralose Solution 25 % (Tate & Lyle)	3 g
	Propylene Glycol	3 g
	Sodium Carbonate	1.5 g
25	Water	6 g
	Oil of Peppermint	4.5 g
	Water portion 1 (hot)	120 g
	Water portion 2 (cold)	120 g

30 The 6 g of water was added to the sodium carbonate, and the mixture was stirred. This mixture was allowed to stir until it was added to the other ingredients later in the process.

Water portion 2 (cold) was placed in an ice bath to chill while water portion 1 (hot) was heated to 60° C and transferred to a stainless steel
 35 container. The 60° C water was stirred with an Arrow Model 1750 high shear

mixer and the Klucel EF gradually added to the water. This solution was stirred for several minutes. Water portion 2 (cold) was then added to the mixture. An ice bath was placed under the stainless steel container, and the mixture was stirred for 15 minutes.

5 After 15 minutes of stirring, the remaining ingredients were added to the mixture one at a time. The mixture was thoroughly blended prior to the addition of the next ingredient. The ingredients were added in the following order: tobacco flavor modifier, propylene glycol, sucralose solution, corn syrup, sodium carbonate solution, sucrose, tobacco powder, B700, and oil of
10 peppermint. Ice was added to the ice bath throughout the mixing process to keep the mixture cold. After all ingredients were added, the mixture was stirred for an additional 10 minutes.

The container was removed from the ice bath and the mixture was dispensed in solid disintegrable portions onto wax paper and allowed to dry at
15 room temperature for 24 hours. The solid disintegrables were removed from the wax paper and transferred to another sheet of wax paper to continue drying at room temperature. The desired hardness for the solid disintegrables was achieved after 12 to 24 hours of continued drying.

20 Example 38. Tobacco Solid Disintegrable

The following ingredients were weighed out into individual containers:

25	HPMC 2910 HM E5/6 Bv (Celanese)	60 g
	Tobacco Powder	75 g
	Tobacco Flavor Modifier	6 g
	Corn Syrup (65 %)	45 g
	Sucrose	45 g
	B700 (Grain Processing Corp.)	39 g
30	Sucralose Solution 25 % (Tate & Lyle)	3 g
	Propylene Glycol	15 g
	Sodium Carbonate	1.5 g
	Water	6 g
	Oil of Peppermint	4.5 g
35	Water Portion 1 (hot)	120 g
	Water Portion 2 (room temp.)	120 g

The 6 g of water was added to the sodium carbonate, and the mixture was stirred. This mixture was allowed to stir until it was added to the other ingredients later in the process.

5 Water portion 1 (hot) was heated to 80° C and transferred to a stainless steel container. The 80° C water was stirred with an Arrow Model 1750 high shear mixer, and the HPMC gradually added to the water. This solution was stirred for several minutes. Water portion 2 (room temp.) was then added to the mixture, and the mixture was stirred for 15 minutes.

10 After 15 minutes of stirring, the remaining ingredients were added to the mixture one at a time. The mixture was thoroughly blended prior to the addition of the next ingredient. The ingredients were added in the following order: tobacco flavor modifier, propylene glycol, sucralose solution, corn syrup, sodium carbonate solution, sucrose, tobacco powder, B700, and oil of
15 peppermint. After all ingredients were added, the mixture was stirred for an additional 10 minutes.

The mixture was dispensed in portions onto wax paper and allowed to dry at room temperature for 24 hours. The solid disintegrables were removed from the wax paper and transferred to another sheet of wax paper to continue
20 drying at room temperature. The desired hardness for the solid disintegrables was achieved after 12 to 24 hours of continued drying.

A similar product was made using the same formulation, mixing process, and dispensing process, but the solid disintegrables were dried in a forced air oven (VWR Model 1330FM) set at 32° C for one hour. The solid
25 disintegrables were then removed from the oven and dried at room temperature for 24 hours. Additionally, solid disintegrables were dried in the forced air oven at 32° C for 18 hours. A slightly harder solid disintegrable with a dull finish was achieved with this drying technique.

Shaped Parts. Tobacco compositions may also be formed into products that are sufficiently rigid to be easily handled. These shaped products may vary in physical properties and range from highly flexible to highly stiff parts. Such products may be formed into any shape and may be dense or foamed.

5 These compositions typically have a moisture content of 2-50%, preferably 5-10%, of the finished part weight. Exemplary shapes include a tube, a toothpick, a stick, a twist, or a solid rod. Alternatively, a shaped part may not have a pre-defined shape. Such an article could be easily shaped by a consumer into any preferable shape. Typically, a shaped part will be sucked or

10 chewed on for an extended period of time to release tobacco organoleptic components into the mouth. A shaped part may or may not disintegrate orally. Parts that disintegrate may do so over a period of 1-60 minutes, preferably from 1-10 minutes.

Shaped parts may or may not be sized to fit entirely in the mouth.

15 Compositions larger than the mouth may be partially inserted. Typically the largest dimension of a shaped part is 6 inches, more preferably 2.5 inches.

Shaped parts may contain discrete regions, e.g., with each region having the same or different flavor or color or size or form of tobacco, e.g., tobacco perceived as soluble. For example, a twist may contain individual strands, each

20 having a different flavor, color, size, or form of tobacco. As further examples, shaped parts may be prepared in multistep processes in which molded or extruded parts are composed of layers, two or more of which contain different flavors, colors, or sizes or forms of tobacco.

Shaped part compositions may be fabricated by any method known in the art, e.g., extrusion, coextrusion, compression molding, injection molding,

25 impact forming, foam molding, blow molding, and overmolding. In addition, shaped parts may be based on water soluble or thermoplastic formats. In one embodiment, an aqueous-based shaped part is fabricated by forming a viscous paste (e.g., via Hobart process) of the format, water, tobacco, and other

30 ingredients and pressing the paste into a form, extruding through a die, or

forming a sheet from which shapes are cut. The cut or formed part may then be dried to the desired moisture level of from 2-50%, preferably from 5-10% of the finished part weight for very rigid parts and from 10-50% for highly flexible parts. In another embodiment, the aqueous paste can be formed in a two stage extrusion process (e.g., via a Wenger twin screw extruder) in which the format, water, tobacco, and other ingredients are blended in a mixing or pre-extrusion stage of the machine, and the resulting paste is fed directly to the twin screw extrusion element of the machine and is extruded through a die to form a shape, which is then dried to the desired moisture level. A thermoplastic-based shaped part is fabricated, for example, by mixing components via a PK blender, high intensity mixer, pre-pelletizer, or granulation (fluid bed or Hobart) process. The mixed components may then be extruded through conventional single or twin screw extruders to form shaped parts or the mixture can be fed into injection molding machines or other thermoplastic processing machinery to form shaped parts.

Shaped Part Examples

Example 39. Injection Molded Shaped Parts

Table 39.1 provides exemplary shaped parts to be formed by injection molding.

Table 39.1.

	1	2	3	4	5	6	7	8
Ingredient	%	%	%	%	%	%	%	%
Tobacco	47.98	45.59	67.18	63.83	78.22	74.32	29.33	27.87
Low viscosity HPC	48.02	45.62	28.84	27.40	19.59	18.61	68.48	65.06
Water	4	3.80	3.98	3.78	2.19	2.08	2.19	2.08
Propylene glycol		4.99		4.99		4.99		4.99

Heating zones were Zone 1 – 300-340 °F; Zone 2 – 350-370 °F; Zone 3 – 300-340 °F; mold temperature was ambient. Sufficient composition was fed to the screw to equal one injection cycle; the material was immediately

injected into the mold; the mold was opened after 10 seconds; and the part was removed. The shaped part was a stepped color chip, 2 inches by 3 inches by steps at 1/8th, 1/4th, and 3/8th inch thickness.

5 Example 40. Compression Molded Shaped Parts

Table 40.1 provides exemplary shaped parts formed by compression molding.

Table 40.1

	A	B	C	D	E	F	G
Ingredient	%	%	%	%	%	%	%
Tobacco	26.47	25.00	25.00	30.00	25.00	25.00	25.00
Corn starch	49.41	30.30		9.50	60.60	30.30	56.60
Starch B-820			30.30				
Maltodextrin						30.30	
Low viscosity HPC				45.00			
Soluble fiber		30.30	30.30				
Cinnamon	4.41	5.00	5.00	5.00	5.00	5.00	5.00
Flavor oil	4.41	5.00	5.00	5.00	5.00	5.00	5.00
Sucralose	0.88	0.90	0.90	0.90	0.90	0.90	0.90
Sodium carbonate	2.65	2.50	2.50	2.50	2.50	2.50	2.50
Glycerin		1.00	1.00	2.00	1.00	1.00	5.00
Propylene glycol	11.77						

10

10-50 grams of water is added per 100 grams of dry compound – sufficient to soften the mix and enable it to pass through a pasta die mounted on a mixer. The mold parameters are as follows:

15 Table 40.2

Mold Temperature	220-280 °F
Residence Time	5 seconds to 60 seconds
Toothpick mold cavity	5/32 inch diameter by 2 3/8 length
Stick mold cavity	3/8 inch diameter by 2 3/8 length
Disc mold cavity	3/4 inch diameter by 1/4 inch depth

Longer residence times produced more rigid parts, as long as the steam was allowed to freely vent during the expansion of the part. Additives may also be employed so that the shaped part remains flexible after removal from the tool. The parts containing a majority of low viscosity HPC formed
5 excellent pieces if left in the tool for an extended time (40 to 60 seconds). The inclusion of plasticizer increased the rate of moisture absorption from the atmosphere, which caused some parts to soften over time.

When the mold cavities were completely filled with molding compound, dense and rigid parts were prepared. When the mold cavities were filled to
10 about 75% of the mold capacity, the compound expanded under the pressure of expanding steam to form foamed parts which had good rigidity, good flavor, and which disintegrated readily in the mouth.

Foaming can be accomplished in aqueous systems by incorporating a surface active agent (e.g., sodium lauryl sulfate) into the mix and beating to
15 incorporate air; foaming or aeration can also be achieved by introducing a gas (e.g., nitrogen) to the aqueous system while the composition is under high shear. The aqueous system is then dried to the desired moisture level to create a stable foamed composition. In one embodiment, an aqueous composition is introduced to partially fill a compression mold; the mold is closed; the mold
20 temperature is raised above the boiling point of water to form steam, which expands the aqueous composition to fill the void area and to create a foamed, shaped part. For thermoplastic systems, foaming can be accomplished by incorporating water into the tobacco/format composition; the temperature is raised to above the boiling point of water to form steam; and, as the tobacco
25 composition exits a die, the steam expands to create a foamed structure. In another embodiment, gas (e.g., nitrogen or carbon dioxide) is introduced into the molten, thermoplastic tobacco composition prior to its discharge from an extruder resulting in a highly uniform foam structure in the shaped tobacco

composition. Other thermoplastic foaming processes well known in the art (e.g., injection foam molding) can be used to create foamed, tobacco compositions and shaped parts.

5 Example 41. Exemplary Aqueous Shaped Parts

Tables 41.1 and 41.2 show exemplary ingredients for fabricating aqueous shaped parts of the invention. Sufficient water is added to form a viscous paste.

10 Table 41.1 (All amounts in parts)

	Exemplary	Preferred	Example
Tobacco	1-80	30-50	54
Flavor	0.5-4	2.5-3	3
Insoluble Fiber	4.5-36	22.5-27	27
Water Soluble Polymer	1-50	5-20	10 CMC 7MF (medium viscosity)
Filler/Disintegrant	1-50	10-30	30 microcrystalline cellulose
Artificial Sweetener	0.05-5	0.1 -2	0.2 Sucralose
Dispersant	0.1-20	0.1-2	0.2 Sodium Lauryl Sulfate

Table 41.2 (All amounts in parts)

	Exemplary	Preferred	Example
Tobacco	1-80	20-50	27
Flavor	0.5-4	1-3	1
Insoluble Fiber	4.5-36	9-27	9
Water Soluble Polymer	1-50	5-25	18 low viscosity HPC
Filler/Disintegrant	1-50	10-30	10 microcrystalline cellulose
Artificial Sweetener	0.05-3	0.1-1	0.5 Sucralose
Dispersant	0.1-20	0.1-2	0.2 sodium lauryl sulfate

Example 42. Exemplary Thermoplastic Shaped Parts

Table 42.1 shows exemplary ingredients for fabricating thermoplastic shaped parts of the invention.

5

Table 42.1 (All amounts in parts)

	Exemplary	Preferred	1	2	3	4
Tobacco	10-80	25-80	76.6	50	25	25
Plasticizer	1-20	1-20	3 propylene glycol	4.6 propylene glycol	5.6 propylene glycol	5
Water Soluble Polymer	10-80	20-50	20	30	40	30 HPC/ 10 sodium alginate
Filler	0-60	0-30	-	15	29	17.5
Stabilizer	0.1-0.5	0.2-0.4	0.4	0.4	0.4	0.5
Flavor	0.1-10	0.2-9	2	4	8	10
In- solubilizing Salt	-	-	-	-	-	2 CaCl ₂

Example 43. Tobacco Rods

A tobacco rod is made from tobacco (54 parts); flavor (2); insoluble
 10 fiber (28); CMC (10); artificial sweetener (0.2); and microcrystalline cellulose
 (30). Water sufficient to form a viscous paste (e.g., 140 parts) is added, and the
 paste is suitable for processing through an extruder. A suitable extruder would
 be a Kitchen Aid mixer fitted with a pasta extruder and die. The rod prepared
 from extrusion through a pasta die can then be used as the forming mandrel for
 15 a spiral winding machine and a tobacco containing film can be used to form a
 wrapping around the tobacco core.

Example 44. Compression Molded Cinnamon Flavored Tobacco Stick

Table 44.1

Tobacco	23.84%
Starch	24.09%
HPMC	4.97%
Flavor	15.90%
Filler	19.27%
Na ₂ CO ₃	2.98%
Sweetener	0.99%
Plasticizer	4.97%
Water	3.00%

- 5 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM100PA2208 (Wolff Cellulosics)	11.16g
10	B700 (Grain Processing Corporation)	55.77g
	Cinnamon Powder	24.54g
	Fibersol-2 (Matsutani)	44.61g
	Na ₂ CO ₃	6.69g
	Sucralose (Tate & Lyle)	2.22g
15	Tobacco Powder (average particle size <80 µm)	55.77g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

20	MIX2	
	Glycerin	11.16g
	Cinnamon Flavor	11.16g

- 25 MIX1 was added to the stainless steel mixing bowl of a Kitchen Aid stand mixer. MIX2 was incorporated slowly to the mixture over a time period of 3 minutes with the aid of a paddle attachment at a medium-low speed. Following this addition, 76.92g of water was added to the mix in the same manner. The resulting paste was allowed to rest at room temperature for a period of 5 minutes.

Following the rest period, the paste was fed through a 1/8 inch aperture strand forming unit which had previously been attached to the Kitchen Aid mixer. The strands produced were cut to between 1 ½ and 2 inches in length, and stored in suitable containers.

- 5 A set of platens with 2 inch by 1/4 inch opposing mold cavities was heated to between 300 – 330 °F. A formed strand was placed in the lower cavity, and the mold was closed by means of a hydraulic press. The mold was allowed to remain closed for a period of 30 – 60 seconds, providing a means for cooking the starch component of the unit and the release of a portion of the
10 volatile components.

The newly formed stick, measuring approximately 2 inches by 1/8 inch, comprised a smooth rigid outer layer, and a rigid foam-like inner mass. The unit disintegrated in the mouth over a period of 1 – 2 minutes.

- 15 Example 45. Compression Molded Apple Flavored Tobacco Stick

Table 45.1

Tobacco	23.84%
Starch	24.09%
HPMC	4.97%
Flavor	6.45%
Filler	19.27%
Na ₂ CO ₃	2.98%
Sweetener	10.42%
Plasticizer	4.97%
Water	3.00%

- 20 The following ingredients were weighed and combined in a container of suitable volume:

	MIX1	
	HM100PA2208 (Wolff Cellulosics)	11.16g
	B700 (Grain Processing Corporation)	55.77g
	Sucrose	22.29g
5	Fibersol-2 (Matsutani)	44.61g
	Na ₂ CO ₃	6.69g
	Sucralose (Tate & Lyle)	1.11g
	Malic Acid	2.22g
10	Tobacco Powder (average particle size <80 µm)	55.77g

The resultant mixture was mixed until homogeneous. In a separate container were weighed the following ingredients:

	MIX2	
15	Glycerin	11.16g
	Apple Flavor	12.27g

MIX1 was added to the stainless steel mixing bowl of a Kitchen Aid stand mixer. MIX2 was incorporated slowly to the mixture over a time period of 3 minutes with the aid of a paddle attachment at a medium-low speed. Following this addition, 76.95g of water was added to the mix in the same manner. The resulting paste was allowed to rest at room temperature for a period of 5 minutes.

Following the rest period, the paste was fed through a 1/8 inch aperture strand forming unit which had previously been attached to the Kitchen Aid mixer. The strands produced were cut to between 1 ½ and 2 inches in length, and stored in suitable containers.

A set of platens with 2 inch by 1/4 inch opposing mold cavities was heated to between 300 – 330 °F. A formed strand was placed in the lower cavity, and the mold was closed by means of a hydraulic press. The mold was allowed to remain closed for a period of 30 – 60 seconds, providing a means for cooking the starch and sugar components of the unit and the release of a portion of the volatile components.

The newly formed stick, measuring approximately 2 inches by 1/8 inch, comprised a rigid outer layer, and a rigid foam-like inner mass. The unit disintegrated in the mouth over a period of 1 – 2 minutes.

5

Example 46. Extruded Tobacco Sticks

Table 46.1

Tobacco	24.34%
Starch	58.48%
Na ₂ CO ₃	3.17%
Plasticizer	6.34%
Sweetener	0.79%
Flavor	4.88%
Water	2.00%

The following ingredients were granulated in a manner similar to granulations utilized for tab production, yielding a tobacco granulation with an approximate moisture of 4.50%:

15	B700 (Grain Processing Corporation)	3327.1g
	B825 (Grain Processing Corporation)	120.0g
	Na ₂ CO ₃	181.4g
	Sucralose (Tate & Lyle)	45.4g
	Glycerin	362.9g
	Tobacco Powder (average particle size <80 µm)	1451.5g
20	Water	3473.0g

The tobacco granulation was introduced to the feed section of a Leistritz Micro-18 Twin Screw Extruder 40:1 L/D, which had been configured for co-rotating extrusion with a medium-shear screw design. Feed rates for the extrusion varied between 1 – 3 pounds per hour. Barrel zone temperatures varied between 75 – 100 °F. Flavor application rates were established at 5 percent of the process flow; hence cinnamon flavor was incorporated to the

process downstream of the granulation feed. Venting of volatiles from the extrusion melt was accomplished by incorporating a venting orifice prior to the discharge die of the extruder.

5 Solid tobacco sticks, with an approximate diameter of 1/8 inch, were produced by incorporating a strand die at the discharge end of the extruder. Upon discharge, the flexible tobacco strand was cooled to room temperature on an air-cooling conveyor, became rigid, and was cut to approximately 2.5 inches in length. The formed tobacco sticks were placed in a suitable container for storage. The stick disintegrated slowly in the mouth over a period of 5 – 10
10 minutes.

Solid tobacco toothpicks, with an approximate diameter of 1/16 inch, were produced by incorporating a strand die at the discharge end of the extruder. Upon discharge, the flexible tobacco strand was cooled to room temperature on an air-cooling conveyor, became rigid, and was cut to
15 approximately 2.5 inches in length. One end of each strand was milled to a sharp point so the part had the appearance and function of a toothpick. The formed tobacco toothpicks were placed in a suitable container for storage. Toothpicks made using Formula 3 from Table 42.1 disintegrated slowly in the mouth and provided tobacco satisfaction over a period of 5-10 minutes.
20 Exemplary toothpicks are shown in Figures 7A-7B.

Toothpicks made using Formula 4 from Table 42.1 were insoluble when placed in the mouth and provided tobacco satisfaction over a period of 5-30 minutes as a result of chewing and sucking on the toothpick. Formula 4 from Table 42.1 includes hydroxypropyl cellulose (30 parts), sodium alginate (10
25 parts), other ingredients (28 parts), tobacco (25 parts), and an insolubilizing calcium salt (2 parts). This formulation was blended and processed through an extruder as described above.

Expanded or foamed tobacco containing toothpicks can be produced by blending a specialty starch such as X-PAND-R starch from Tate & Lyle with
30 tobacco, a standard starch, and water as shown in Table 46.2. The components

are thoroughly mixed and heated to cause expansion of the X-PAND-R starch. Once dried, the expanded parts have a smooth, dense outer surface surrounding a foamed core. The blended components can be shaped, processed and heated in many types of conventional equipment, as described herein.

5

Table 46.2. Tobacco Shapes

	Exemplary (parts)	Preferred(parts)
Tobacco	30-95	40
XPAND-R Starch (Tate & Lyle)	1-10	5
Starch	10-30	20
Water	10-60	35

Table 46.3. Tobacco Shapes

	Exemplary (parts)	Preferred(parts)
Tobacco	30-95	40
XPAND-R Starch (Tate & Lyle)	1-10	5
Water	10-60	55

10

The formulation of Table 46.3 forms a composition that can be easily shaped by a consumer into a moist cohesive portion, e.g., by pressing a small amount of the mixture between the fingers; this portion is then conveniently and cleanly placed in the mouth. This portion will retain its shape until tobacco satisfaction is achieved and the portion is removed and discarded. This cohesive property is obtained by utilizing the adhesive characteristics of starch, modified starch, maltodextrin, dextrosem or a combination of these or similar materials when they are added to tobacco in the presence of water. Certain water-soluble polymers, gums, or hydrocolloids, e.g., karaya gum or psyllium seed, can be used in place of the starch or modified starch to achieve similar results.

20

Gels and Gel Beads. Compositions of the invention may also be made as gels or gel beads. The composition may contain a soluble or insoluble gel containing tobacco. A gel may be used to encapsulate another material, or another material may encapsulate a gel. Gels may be consumed in hydrated
5 forms containing as much as 70% water. The gels may also be dried resulting in parts containing from 1 to 70% water. The amount of water retained in the gel depends on the properties desired in the finished product. It is possible to prepare tobacco containing gels that provide a wide range of organoleptic characteristics.

10 Exemplary gel formats for soluble and insoluble gels include kappa carrageenan, sodium alginate, carboxymethyl cellulose, gelatin, pectin, agar, and starches.

Soluble gels containing tobacco can be formed by dissolving the format at an elevated temperature, e.g., kappa carrageenan at 180°F, and adding the
15 tobacco powder to this solution while continuing vigorous mixing. The hot mixture is then deposited into a mold. Gelatin provides a weak gel at room temperature but firmness and stability can be increased by the addition of agar or starches. Other gelling formats may be used in a similar manner. Exemplary soluble gels are shown in Figures 8A-8B.

20 Insoluble gels are formed by the addition of a cross-linking agent to a predissolved solution or slurry. The solution is deposited into a mold to form the desired shape and sets up through cooling and/or drying. In most cases, it is necessary to maintain the solution at a high temperature, e.g., greater than 180 °F, to prevent premature gelation prior to deposition into the mold. After
25 the gel has set into its final shape, the gel can be packaged as is or be further dried to a desired water content. Cross-linking agents include potassium ions for carrageenan; calcium ions for alginates and low methoxy pectins; and trivalent ions such as aluminum for carboxymethyl cellulose. In insoluble gels (i.e., those that do not orally disintegrate), tobacco organoleptic compounds
30 may leach out of the gel as it is held or chewed in the mouth.

In one embodiment, gel compositions, e.g., beads, have a solid or liquid center. An exemplary solid center includes smokeless tobacco. An interior liquid may be aqueous, non-aqueous, or heterogeneous, depending on the solubility characteristics of the encapsulating bead wall. Aqueous based liquids are typically encapsulated in a water-insoluble gel that can be disrupted, either mechanically or chemically, in the mouth. The encapsulating gel format may include a polymer and a cross linking agent. Exemplary systems include carrageenan and a potassium salt, alginate or pectin and a divalent ion (e.g. calcium), carboxymethyl cellulose and a trivalent ion (e.g. aluminum), and gelatin and gum arabic. The center may or may not include tobacco.

In another embodiment, a water soluble gel encapsulates a non-aqueous filling, e.g., employing ethanol, glycol, vegetable oil, or mineral oil. The water soluble gel and/or the non-aqueous filling may contain tobacco and other ingredients as described herein. Aqueous liquids may also be encapsulated in water soluble gels by the inclusion of additives, e.g., sugars or salts, that sufficiently bind the available water in the filling, thus, preventing the water in the liquid from dissolving the encapsulant. Gel encapsulants also include both hard and soft standard gelatin capsules, which can be filled with liquids or solids.

The center of these gel compositions may or may not include tobacco, e.g., as a tobacco slurry. The gel encapsulant also may or may not include tobacco. An exemplary solid center includes smokeless tobacco. The center may also include a color, sweetener, flavor, or flavor masking agent, which may be the same or different from that of the gel encapsulant. The rate of disintegration for the gel encapsulant and center may also be the same or different. Gels with centers typically have a largest dimension of at most 10 mm, preferably at most 5 mm. Gel beads with liquid centers may be made by introducing droplets of a tobacco/format mixture into a solution causing gelation of the outer surface of the gel bead and retaining the liquid center. Beads can be formed using commercial processes developed by the Morishita

Jintan Company and others and referred to generically as “seamless liquid encapsulation” or “seamless capsule technology.” In addition, widely used methods for forming gels of all types including beads have been developed by the suppliers of alginate, carrageenan, and pectin polymers and are well known in the art. The amount of gelation may be controlled, thereby controlling the thickness of the gel encapsulant wall, by varying the concentration of the format, the concentration of the cross-linking agent (e.g., salt), the temperature of the solidifying solution, and the residence time of the gel bead in the solidifying solution. The solution may contain a cross-linking agent or may induce gelation by other means, e.g., a temperature change. Exemplary gel beads are shown in Figures 9A-9B.

Solid gels may be soluble or insoluble. For solid gels, the tobacco and format, with or without additives, are typically mixed, and the format is allowed to gel. Soluble gels can be obtained by using a self gelling gum, such as gellan gum or kappa carrageenan, or by using a polymer, e.g., gelatin, that sets by a change of temperature. Insoluble solid gels are prepared using a cross linking agent. Such soluble and insoluble gels may be made by introducing droplets into an oil bath, e.g., canola oil, or into an aqueous, cross-linking bath to form a spherical shape. They may also be made to pass through the oil into a water based cross-linking solution. Gels may also be made in molds or may be die cut from sheets.

In another embodiment, a gel composition is supplied as a dry mixture of format, cross-linking agent (e.g., salt), and tobacco, e.g., in powder form, that is solvated by the consumer prior to use. Solvation causes the gel composition to form a solid, which may be placed in the mouth. Typically, the user places the dry mixture of gel ingredients in a mold and adds solvent, which may be aqueous or non-aqueous. The mixture then quickly hydrates, thereby forming a gel which solidifies in the shape of the mold. The solvating liquid may be used to impart flavor or other taste or mouth feel characteristics

to the composition. Alternatively, the consumer may place the dry mixture in the mouth for solvation. The solvent may impart flavor or color to the composition.

5 Gel Examples

Example 47. Gel Beads

100 g of 4% solution of CMC-7MF and 20 g tobacco are combined. Drops are deposited into a 5% solution of water soluble, edible trivalent salt (e.g., AlCl_3 , $\text{Al}_2(\text{SO}_4)_3$, or basic aluminum acetate. The surface of droplets is then dried with air drying or gentle oven drying.

100 g of 2% kappa carrageenan and tobacco are combined and heated to 180–190 °F. Drops are deposited into a cool solution of 5% KCl.

100 g of 4% medium viscosity sodium alginate, disodium hydrogen phosphate heptahydrate, and tobacco are combined at 150-170 °F. Drops are deposited into a cool solution of 5% edible divalent salt (e.g., CaCl_2 or Ca citrate).

Beads containing gelatin walls and tobacco slurry centers can be prepared by depositing drops of a cold tobacco slurry (e.g., 60 °F) into a slow moving stream of a dilute, warm gelatin solution (e.g., 130 °F). The warm gelatin coats the outside of the cold droplet and as the gelatin cools and solidifies, it forms a wall of gelatin around the liquid center.

Beads are retrieved from the solution by standard means.

Example 48. Orally Disintegrable Solid Gels

25 Combine 10 g gelatin and 90 g water and heat to 140 °F to dissolve gelatin. Add 20 g tobacco and pour into a mold. Strength of the gel can be increased by substituting 6 g of gelatin and 4 g of agar and heating to 190 °F to dissolve.

Table 48.1 shows exemplary ingredients for fabricating orally disintegrable gels of the invention.

Table 48.1

	Example 1 (parts)	Example 2 (parts)
Gelatin	8	6
Tobacco	40	40
Flavor	2	2
Insoluble Fiber	18	18
Sweetener	0.2	0.2
Agar	4	6
Soluble Fiber	15	15
Preservative	0.1	0.1
Water	200	200

5

Example 49. Exemplary Insoluble Solid Gels

The following tables and descriptions show exemplary ingredients for fabricating insoluble gels of the invention, i.e., gels that do not orally disintegrate.

10

Table 49.1. Carrageenan Gels

Ingredient	Parts
Kappa Carrageenan	8
Water	240
Tobacco	54
Sweetener	0.5
Soluble Fiber	27
KCl	1.5

The composition is cast at 180 °F after adding KCl and mixing thoroughly.

Table 49.2. Alginate Gels

Ingredient	Parts
Sodium Alginate	10
Water	240
Na ₂ HPO ₄ · 7 H ₂ O	10
Tobacco	54
Sweetener	0.5
Soluble Fiber	27
CaCl ₂	1

The composition is cast after adding CaCl₂ at 180 °F.

Table 49.3. Carboxy Methyl Cellulose Gels.

Ingredient	Parts
CMC-7MF	10
Water	240
Tobacco	54
Sweetener	0.5
Soluble Fiber	27
Al ₂ (SO ₄) ₃	1

5 The composition is cast after adding Al₂(SO₄)₃ at 180 °F.

Example 50. Soluble Gels

416 grams of aqueous 3.9% kappa carrageenan and 51.0 grams of tobacco were combined. The solution was heated to 180° F - 190° F with stirring, and then the solution was deposited into a mold of the desired shape. Upon cooling, the resultant solid form was removed from the mold and dried to the desired tobacco concentration and gel consistency.

In an alternative process, to a 1000 ml stainless steel container equipped with an overhead mixer, mixing bar, and hotplate was added 400 ml of water at greater than 200° F. The water was continuously stirred and heated, and 16.0 g of kappa carrageenan (Gelcarin GP 812, FMC Biopolymer) was added over 2 minutes. The resulting mixture was stirred for an additional 20 minutes or until all kappa carrageenan was dissolved; then tobacco was added to the homogeneous solution, and the resulting mixture was stirred for an additional 2 minutes while maintaining an optimal temperature of 180° F. To this solution

was added 0.8 g powdered Sucralose and 7.0 g cinnamon oil (Wixon Industries) with vigorous stirring. Following an additional 1 minute of stirring, the resulting mixture was quickly transferred via pipette (inner diameter 0.5 cm) to Teflon-coated metal molds to obtain the desired shape. After cooling to room temperature, the resulting gels were removed from the molds and air dried at room temperature for 1 h to several days until the desired consistency of the gels was obtained.

Table 50.1. Carrageenan Gels

Ingredient	Parts
Kappa Carrageenan	16
Water	400
Tobacco	51
Sweetener	0.8
Cinnamon Oil	7.0

Example 51. Soluble Gels

100 grams of aqueous 20% gelatin and 33 grams of tobacco were combined. The solution was heated to 140° F - 150° F with stirring, and then the solution was deposited into a mold of the desired shape. Following refrigeration for a few minutes to a few days depending on desired firmness, the resultant solid form was removed from the mold and dried to the desired tobacco concentration and gel consistency.

In an alternative process, to a 400 ml stainless steel container equipped with an overhead mixer, mixing bar, and hotplate was added 80 ml of water at 140° F. The water was continuously stirred and heated, and 20.0 g of Gelatin (Type A 250 Bloom 40 Mesh, Gum Technology) was added over 2 minutes. The resulting solution was stirred for 5 minutes or until the gelatin was dissolved, then 33 g of tobacco was added in portions over 2 minutes. The resulting mixture was stirred for an additional 1 minute, then 0.3 g powdered Sucralose and 1.0 g of oil of peppermint (rectified, Blend SX 0910001, Essex Labs) were added, and the mixture was vigorously stirred for an additional 1 minute while maintaining a temperature of 140° F. The resulting mixture was

transferred via pipette (inner diameter 0.5 cm) to Teflon-coated metal molds to obtain the desired shape. After cooling to room temperature, the resulting gels were removed from the molds, and the gelatin was set by refrigeration at 40° F for 1 hour to several days depending on desired firmness of the finished piece.

5

Table 51.1. Gelatin Gels

Ingredient	Parts
Gelatin	20
Water	80
Tobacco	33
Sweetener	0.3
Peppermint Oil	1.0

Example 52. Gel Beads

A solution of 4% sodium alginate (Keltone LV, International Specialty Products) was prepared by adding 12 g sodium alginate to 288 g of water heated to boiling, followed by stirring and continuous heating of water on a hot plate for 30 minutes or until the solution was homogeneous (stock solution A; Table 52.1). A second solution of 0.50 M disodium hydrogen phosphate was prepared by dissolving 33.5 g disodium hydrogen phosphate heptahydrate in 200 ml of water with warming and stirring of the resulting mixture until the salt was dissolved, followed by adjusting the solution to 250 ml with water. To 100 g of aqueous 0.50 M disodium phosphate was added 20 grams of tobacco and the resulting solution was stirred for 5 minutes (stock solution B; Table 52.2). To 50 g of the resulting tobacco slurry (stock solution B) was added 50 ml of aqueous 4% sodium alginate (stock solution A), and the resulting mixture was stirred for 5 minutes. To flavor, 0.20 g of powdered Sucralose and 0.80 g of oil of peppermint (rectified, Blend SX 0910001, Essex Labs) were added to the resulting tobacco/sodium alginate slurry (solution C; Table 52.3), and the mixture was stirred for 2 minutes.

To prepare gel beads from solution C, a solution of aqueous 5% CaCl_2 was prepared by adding 5 g of CaCl_2 to 95 g of water with stirring until the calcium chloride was dissolved (solution D; Table 52.4). Solution C was then

added drop by drop to solution D by pipette from a height of 10 inches. The outer coat of each droplet solidified upon exposure to solution D, forming a solid gel-like outer coat with a liquid center that sank to the bottom of the calcium chloride solution. The gel beads were allowed to remain in the calcium chloride solution for 2-4 minutes, removed, and allowed to air dry for several minutes.

Table 52.1. Solution A

Ingredient	Parts
Sodium alginate	12
Water	288

10 Table 52.2. Solution B

Ingredient	Parts
$\text{Na}_2\text{HPO}_4 \cdot 7 \text{H}_2\text{O}$	13.4
Water	86
Tobacco	20

Table 52.3. Solution C

Ingredient	Parts
Solution A	50
Solution B	50
Sucralose	0.2
Oil of peppermint	0.8

Table 52.4. Solution D

Ingredient	Parts
Calcium chloride	5
Water	95

15

Consumable Units. Compositions of the invention may also be fabricated as consumable units. These units may be packaged as edible or inedible materials. In one embodiment, the consumable unit includes tobacco (e.g., smokeless tobacco) or a tobacco composition, e.g., flakes, tabs, beads, granules, or other tobacco composition as described herein, and a wrapping, e.g., a pouch. The wrapping, in one embodiment, may act as an adhesive to hold the composition together, e.g., to hold a plurality of tabs, beads, flakes,

20

etc. together. Alternatively, the wrapping may enclose the composition, e.g., loose tabs, beads, flakes, etc. The composition may also include a liquid, e.g., a tobacco slurry. The wrapping may or may not be orally disintegrable. Orally disintegrable wrappings may be used to enclose aqueous or non-aqueous liquids. When an aqueous liquid is employed with a water soluble wrapping, the liquid includes an agent to prevent dissolution of the wrapping. Exemplary agents include sugars, salts, and other hydrophilic agents capable of binding water sufficiently to reduce water activity to a level at which the water is no longer available to interact with and dissolve the water soluble wrapping. The wrapping may also enclose a moldable tobacco composition that conforms to the mouth or holds its shape in the mouth. In one embodiment, an orally disintegrable wrapping encloses smokeless tobacco, e.g., dry snuff or tobacco, that is perceived as soluble (e.g., less than 80 μm particle size), as shown in Figures 10A-10B. Orally disintegrable smokeless tobacco compositions may be introduced to consumable portion packs which have been formed on continuous thermoforming or horizontal form/fill/seal equipment or other suitable packaging equipment using edible films (which may or may not contain tobacco) made in accordance with the subject technology. Consumable units may also contain two or more, individually wrapped portions of tobacco, e.g., all contained within a larger package, one containing the other portions, or none of the portions contained with another. When multiple portions are used, any two may have the same or different flavor, color, form of tobacco, or rate of disintegration.

Exemplary wrapping materials include films formed from film compositions based on formats such as HPMC, CMC, pectin, alginates, pullulan, and other commercially viable, edible film forming polymers, such as those described herein. Other wrapping materials may include pre-formed capsules made from gelatin, HPMC, starch/carrageenan, or other commercially available materials. Such wrapping materials may include tobacco as an ingredient. Wrappings which are not orally disintegrable may include woven

or nonwoven fabrics; coated or uncoated paper; or of perforated or otherwise porous plastic films, as shown in Figures 11A-11B. Wrappings may also be colored. Exemplary consumable units include those formed by any method used in commercial packaging, e.g., blister pack and stik-pak (e.g. a small
5 package formed on a vertical form/fill/seal packaging machine).

Consumable Unit Examples

The following description provides exemplary ingredients for fabricating consumable units of the invention.

10

Example 53. Films or Capsules Encapsulating Beads, Powders, Tabs, Etc.

Any of the compositions described herein can be encapsulated with a film or capsule. The encapsulant may provide color, stability (e.g., during storage, handling, or consumption), or organoleptic properties (e.g., flavor,
15 sweetness, smell, or mouth feel). The encapsulant may also contain tobacco.

A vacuum forming tool is constructed which has a series of cavities which are shaped as circles with diameter of 3/4 inch and depth of 3/8 inch. Films as described herein are prepared with and without tobacco as an ingredient. These films are introduced to a vacuum forming machine with a
20 vacuum forming tool. The films are placed over heating elements and warmed to a temperature of 200 °F. The films are then quickly placed on the vacuum forming tool, and a vacuum is pulled to draw the film into the cavities. The films are then cooled to set the shapes. Tobacco powder is then introduced into each cavity. A second sheet of film prepared with or without tobacco is
25 selected and coated (by wiping the surface of the film with a wet felt) with a thin layer of water to create a sticky, adhesive surface. The sticky surface is placed on top of the formed sheet wherein each cavity is filled with a tobacco product. The sheets are pressed together to form closed consumable units.

Each cavity is then cut out of the vacuum formed sheet to create individual units. A unit is placed in the mouth wherein the film disintegrates and disperses the tobacco in the oral cavity.

5 Example 54. Tobacco Particles in a Water-soluble Bag

Smokeless tobacco particles or powder, e.g., snuff, may be placed in a water-disintegrable bag. When placed in the mouth, the bag disintegrates after a specified period of time. The bag may contain a single serving of tobacco. It may also contain additional additives as described herein. The tobacco may
10 also adhere to itself as a moldable plug once the wrapping disintegrates.

The disintegrable bag may be formed using films such as those described herein. The film can be formed into a bag using commercially available packaging equipment such as vertical form/fill/seal machines (e.g. stick pack machines), horizontal form/fill/seal machines, flow wrappers,
15 thermoformers (blister pack machines), and other equipment common to the art.

Example 55. Tobacco particles in film/fabric laminations

Smokeless tobacco particles or powder may be placed in a bag that is
20 formed from an open or highly porous wrapping material, e.g., fabrics, paper or plastic films, which has been laminated to a water-soluble wrapping film. The water-soluble film layer provides protection for the tobacco contents and prevents the tobacco from sifting through the openings of the insoluble material during storage and handling. Once the bag is placed in the mouth, the water-
25 soluble film layer dissolves or disintegrates.

Example 56. Film Pouches Containing Tobacco

Films as described herein in Film Examples 14-18 were used to manufacture tobacco containing pouches. Individual units approximately 1
30 inch by 1 ¼ inches were cut from each sheet of manufactured film. The unit

was folded over lengthwise and heat-sealed using a Clamco Model 210-8E impulse sealer. One end of the formed unit was also sealed in the same manner. A flavored tobacco granulation was fed to the interior of the formed pouch, and the final seal was made as described to seal the pouch. The tobacco
 5 containing pouch disintegrated in the mouth between 20 seconds and 1 minute, releasing the contents of the pouch.

Tables 56.1 and 56.2 list ingredients for exemplary film pouches.

Table 56.1 Mint Flavored Film Pouches Containing Tobacco

Ingredient	Percentage (dry weight)
Maltodextrin M585	27.02%
Mannogem TM 2080 Granular USP/FCC	22.81%
Tobacco	16.58%
Klucel EF Hydroxypropylcellulose	8.18%
Walocel HM100PA2208 Hydroxypropylmethylcellulose	4.10%
B700 Modified Food Starch	3.98%
Fibersol-2	3.06%
Mint Flavor Oil	2.84%
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	1.61%
Glycerin	1.61%
Propylene Glycol	1.61%
Triacetin	1.45%
Sodium Carbonate	1.40%
Gum Arabic Prehydrated FT	0.83%
Walocel HM4000PA2910 Hydroxypropylmethylcellulose	0.69%
Natural Tobacco Enhancer 631536	0.64%
Sodium Chloride	0.53%
Ammonium Carbonate	0.40%
Sucralose (from Liquid Concentrate 25%)	0.16%
Grindsted Propylene Glycol Monostearate USV-K	0.13%
Sodium Lauryl Sulfate	0.13%
Spearmint Flavor Oil	0.11%
Sucralose	0.08%
FD&C Blue Alum Lake 35-42%	0.06%

Table 56.2 Cinnamon Flavored Film Pouches Containing Tobacco

Ingredient	Percentage (dry weight)
Maltodextrin M585	28.84%
Lactose Refined Edible	20.64%
Tobacco	16.82%
Klucel EF Hydroxypropylcellulose	8.18%
Walocel HM100 PA2208 Hydroxypropylmethylcellulose	4.10%
Pure-Dent B700 Modified Food Starch	3.98%
Fibersol-2	3.06%
Cinnamon Flavor Oil	2.41%
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	1.61%
Glycerin	1.61%
Propylene Glycol	1.61%
Triacetin	1.45%
Sodium Carbonate	1.41%
Gum Arabic Prehydrated FT	0.88%
Walocel HM4000PA2910 Hydroxypropylmethylcellulose	0.69%
Natural Tobacco Enhancer 631536	0.64%
Cinnamon Flavor Oil	0.55%
Sodium Chloride	0.54%
Ammonium Carbonate	0.41%
Sucralose (from Liquid Concentrate 25%)	0.16%
Grindsted Propylene Glycol Monostearate USV-K	0.13%
Sodium Lauryl Sulfate	0.13%
Sucralose	0.08%
FD&C Red 40 Alum Lake 35-42%	0.06%

Insoluble Matrices. Tobacco may also be coated onto or entrapped within an insoluble matrix. Tobacco can be dispersed to form a slurry in an aqueous solution of a format, as when forming a film; this slurry can be coated on to an insoluble matrix or can be used to saturate a porous insoluble matrix. The slurry may then be converted into a soluble or insoluble gel or it may simply be dried to form a coating. When a portion of this coated/saturated insoluble matrix is placed in the mouth, leaching of organoleptic components occurs through dissolution, chewing, or other means. In one embodiment, tobacco in a format is introduced into a porous matrix, e.g., an open cell polyurethane foam or a high loft polyester nonwoven fabric. The insoluble matrix may be placed wholly in the mouth, or it may be disposed on a stick or other handle, which remains partially outside the mouth during consumption. In another embodiment, tobacco in a format is blended with an incompatible

liquid, e.g., a dispersion of carnauba wax in water, deposited in a mold, and quickly cooled to cause a phase separation such that the tobacco slurry is disposed within a waxy structure. These matrices may also be chewable. The insoluble matrix may be dried to a desired moisture level, e.g., less than 20%
5 by weight and more typically to about 5% by weight.

In yet another embodiment, tobacco is blended with an insoluble thermoplastic powder (e.g., low MW polyethylene beads), and a suitable level of flavor, sweetener, and plasticizer. This dry blend is loaded into a mold which is closed in a manner that applies pressure to the mixture. The mold is
10 energized with heat, microwave, UV, radio frequency, or similar energy sources sufficient to soften the thermoplastic polymer and cause it to form (e.g., sinter) into a porous, rigid structure. The porosity or "open area" in the finished part is determined by the particle geometry of the thermoplastic polymer, the concentration of the thermoplastic polymer, and the pressure
15 applied. An exemplary porous part is placed in the mouth where tobacco satisfaction and flavor are leached from the porous part through dissolution, chewing, or other means. After use, the porous part is removed from the mouth and discarded.

Formats for use in retaining the tobacco in the insoluble matrix include
20 any of the film forming polymers described herein; any of the gelling systems described herein and any of the coating materials described herein.

Insoluble Matrix Examples

Example 57. Polyurethane Foam A

25 A film forming composition which contains finely ground tobacco as described herein is used to saturate a piece (e.g., 12 inches by 12 inches by 1 inch) of open cell polyurethane foam (Stephenson & Lawyer, Inc. Grand Rapids, MI). The saturated foam is placed on a metal tray and is put into an air circulating laboratory oven preset at 175 °F for one hour. When the foam is
30 removed from the oven, the tobacco containing composition has dried to form a

coating that uniformly covers all the interstices of the polyurethane foam. The coated foam is cut into pieces of a size (e.g., 1 inch by 1 inch by 1 inch) suitable to place in the mouth. After use, the polyurethane foam is removed from the mouth and discarded.

5

Example 58. Polyurethane Foam B

A sodium alginate and calcium salt gel composition containing finely ground tobacco as described herein is used to saturate an open cell polyurethane foam (e.g., 12 inches by 12 inches by 1 inch). The alginate gel is maintained at a temperature of 180 °F to prevent premature setting of the gel. The hot alginate gel is poured on to the polyurethane foam, which is placed on a metal tray and then quickly cooled in a refrigerator at 40 °F to set the gel. The foam is then placed in a laboratory oven preset at 175 °F for 10 minutes to surface dry the gel and to reduce moisture content to 50% based on dry weight of the gel. The partially dried gel fills voids in the polyurethane foam. The foam is cut into pieces and is placed in the mouth. A further example of gels in an insoluble matrix is obtained by drying the gel to a lower moisture content (e.g., 10% based on dry weight of the gel). The tobacco containing gel exhibits a firm, rubbery texture within the foam matrix and rehydrates slowly when placed in the mouth and chewed. After use, the polyurethane foam is removed from the mouth and discarded.

Example 59. Molded Tobacco on an Insoluble Matrix

Smokeless tobacco, e.g., in shredded form, is mixed with pellets or granules of a low molecular weight polyethylene (Alathon™, DuPont). The ratio of tobacco to polyethylene (or other insoluble format) may be 99:1 to 50:50, e.g., 95:5 to 90:10. The mixture is heated to a temperature of about 90 °C and molded into a shape, e.g., a cylindrical shape with dimensions of 0.5 – 0.9 inches, e.g., approximately 0.75 inches, in diameter and 1 – 3 inches, e.g., approximately 2 inches, long. The shape typically has an opening for the

insertion of a wooden handle, which may be inserted while the mixture is being heated. Heating continues until the moisture content of the mixture is reduced to about 3 – 30 %, e.g., 5%. The mixture is then allowed to cool and to adhere to the wooden handle. The user will insert the molded tobacco and polymer
5 mixture into the mouth using the handle. After use, the product is discarded.

Example 60. Molded Tobacco on an Insoluble Matrix

A thin layer of smokeless tobacco, e.g., in shredded form, is prepared on a conveyor and sprayed on one side with a hot melt polymer, such as a wax, to
10 coat the tobacco partially. The ratio of tobacco to wax (or other insoluble format) may be 99:1 to 50:50, e.g., 95:5 to 90:10. Once the partially coated tobacco is dried or cooled, it is compressed in a mold at a moderate temperature (e.g., 25 °C to 150 °C) and pressure (e.g., 2 kN – 20 kN) to form a shape, e.g., a tube 1 – 3 inches, e.g., approximately 2 inches, long with a
15 diameter of 0.5 – 0.9 inches, e.g., approximately 0.75 inches. The shaped product contains a substantial external area of uncoated tobacco. The coated surfaces bind the tobacco, and the uncoated surfaces provide tobacco satisfaction to the user. A shaped product is inserted into the mouth of the user and discarded after use. In addition, the shaped product may include a handle,
20 e.g., a wooden, paper, or plastic stick, as described above.

Hollow Shapes. As discussed above, films or thin sheets of material may be wrapped, extruded, blow molded, or otherwise shaped to form tubes, straws, or other hollow shapes. Exemplary film or sheet materials are disclosed
25 in the film section herein. Such hollow shapes may be single or multilayer. When multiple layers are used, some may contain tobacco while others may contain colors, flavors, sweeteners, or other compounds as described herein. Different layers may also be employed for stability during handling or to control disintegration during consumption. A spiral wrapped hollow shape,
30 e.g., tube or straw, may require an adhesive (e.g., CMC, guar, or gum arabic) to

keep from unraveling. The layers in a multilayer hollow shape may contain the same or different color or flavor, and such layers may disintegrate at the same or different rates. As with films, tobacco may also be disposed within one or more layers or may be disposed between layers in a sandwich arrangement.

- 5 The hollow shape may also include a disintegrant to hasten disintegration. Exemplary straws and sticks are shown in Figures 12A-12B, 13A-13B, and 14A-14B.

The compositions described above may be hollow or filled. The filling may include tobacco, a flavor, sweetener, flavor masking agent, or a color. The
10 flavor or color of the filling may be the same or different than the hollow shape. The filling is typically a gel (solid or flowable) but may also be mechanically rigid or may be composed of a powder or other product form. Exemplary filling materials include gels as described herein. A white, opaque straw containing a tobacco filling is shown in Figure 14A-14B. A hollow
15 shape may also be filled with a composition that disintegrates more rapidly than the shape, e.g., to provide tobacco at different times based on the rate of disintegration.

In one embodiment, a tobacco core (e.g., formulated with tobacco and a format) can be extruded from a single or twin screw extruder into a coextrusion
20 die. In a separate single or twin screw extruder, a water soluble, thermoplastic outer layer (e.g., formulated with a format and a flavor) can be introduced to the coextrusion die to create a coated rod. A typical thermoplastic outer layer can be provided with a formulation based on hydroxypropyl cellulose (HPC) which is extruded at a temperature of 200-370 °F. In addition, a rigid extruded
25 tobacco rod may become a core which is encased in a wrapped film.

In one example, a thermoplastic formulation containing hydroxypropyl cellulose, tobacco, flavor, and sweetener can be blow molded to form a hollow shape.

In another example, films as described herein were additionally used to manufacture spiral-wound straws and/or sticks. Strips of film approximately 10 inches by $\frac{3}{4}$ inch were cut from each sheet of manufactured film. A strip of paper of equal size was cut and wound spirally around a $\frac{3}{16}$ inch diameter stainless steel mandrel. The paper was secured about the mandrel with tape on each end. A strip of film was wound spirally about the paper in the same fashion, overlapping each spiral by $\frac{1}{16}$ inch. At each overlap the film strip was glued to itself with a 30% solution of gum arabic. The process was repeated with two additional plies of film. The mandrel and newly formed spiral-wound film straw/stick was placed in a side-swept forced air oven at 75°C (VWR model 1330FM) for 15 minutes to dry. Upon removal from the oven, the spiral-wound straw/stick was removed from the mandrel, and the paper "core" removed from the interior of the straw/stick. The resultant straw/stick was cut into various sizes. Similar articles can be manufactured commercially using spiral-winding machinery known to the trade.

For example, spiral-wound straw/stick products were prepared using tobacco containing films as described in Example 14. Straw/stick products containing one layer, two layers and three layers of Example 14 films were prepared as described. When placed in the mouth, the straw/stick disintegrated gradually over a period of 1 to 5 minutes. Similar articles can be manufactured commercially using spiral-winding machinery known to the trade.

In another example, straw/stick products were prepared using two layers of film as described in Example 14. A third layer of film, prepared as described in Example 15 was provided on the top or outside of the straw/stick. The film from Example 15 was red in color, cinnamon flavored, and did not contain tobacco. This straw/stick, when placed in the mouth, disintegrated gradually over a period of 1 to 5 minutes. Similar articles can be manufactured commercially using spiral-winding machinery known to the trade.

In another example, straw/stick products were prepared using three layers of film as described in Example 17. The film from Example 17 contained tobacco powder and peach puree. The straw/stick was prepared as above. The straw/stick, when placed in the mouth, disintegrated gradually over a period of 1 to 5 minutes.

In yet another example, straw/stick products were prepared using three layers of film as described in Example 14 and Example 18. One layer of tobacco containing film prepared in Example 14 was used. A second layer of opaque, white film prepared as in Example 18 was wound over the first layer of film and offset by 1/8 inch. A third layer of tobacco containing film as prepared in Example 14 was wound over the second layer and again was offset by 1/8 inch. The effect was to provide a spiral-wound straw/stick with a striped appearance. The straw/stick, when placed in the mouth, disintegrated gradually over a period of 1 to 5 minutes.

15

In another example, hollow tobacco straws, with diameters ranging from 1/8 to 1/4 inch, were produced by methods similar to those employed in Example 46 of Shaped Parts; however, a tube die was employed in the manufacture of the straw. The straw(s) disintegrated slowly in the mouth over a period of 5 – 10 minutes. Similar articles may be manufactured with a filling, with methods known in the art (i.e., co-extrusion).

20

Tables 61.1 and 61.2 list the ingredients for exemplary multilayer straws.

Table 61.1 Mint Flavored Multilayer Straw

Ingredient	Percentage (dry weight)
Klucel EF Hydroxypropylcellulose	25.45
Tobacco	18.94
Walocel HM100PA2208 Hydroxypropylmethylcellulose	12.74
B700 Modified Food Starch	12.38
Mint Flavor Oil	6.50
Propylene Glycol	4.04
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	3.62
Glycerin	3.62
Fibersol-2	2.23
Walocel HM4000PA2910 Hydroxypropylmethylcellulose	2.14
Sodium Carbonate	2.12
Natural Tobacco Enhancer 631536	1.97
TiO ₂ (from 50% dispersion 58011)	1.00
Sodium Chloride	0.61
Triacetin	0.59
Grinsted Propylene Glycol Monostearate USV-K	0.55
Sodium Lauryl Sulfate	0.55
Sucralose (25% liquid concentrate)	0.49
Ammonium Carbonate	0.46

5 Table 61.2 Cinnamon Flavored Multilayer Straw

Ingredient	Percentage (dry weight)
Klucel EF Hydroxypropylcellulose	25.45%
Tobacco	18.94%
Walocel HM100PA2208 Hydroxypropylmethylcellulose	12.74%
B700 Modified Food Starch	12.38%
Carbowax Sentry Polyethylene Glycol 400 NF, FCC Grade	4.92%
Glycerin	4.49%
Cinnamon Flavor Oil	4.33%
Propylene Glycol	4.04%
Fibersol-2	2.23%
Walocel HM400 PA2910 Hydroxypropylmethylcellulose	2.14%
Sodium Carbonate	2.12%
Natural Tobacco Enhancer 631536	1.97%
TiO ₂ (from 50% dispersion 58011)	1.00%
Sodium Chloride	0.61%
Triacetin	0.59%
Grindsted Propylene Glycol Monostearate USV-K	0.55%
Sodium Lauryl Sulfate	0.55%
Sucralose (25% liquid concentrate)	0.49%
Ammonium Carbonate	0.46%

Example 61. Three Ply, Spiral Wound Stick

A three ply, spiral wound stick is prepared using three different films as described herein. The outer layer contains tobacco (e.g., 30-60% by weight, preferably about 40% by weight) and flavor and sweetener. This layer is
5 approximately 1.5 mils (37 microns) in thickness and is prepared at pH of about 8.5. The middle layer contains tobacco (e.g., 10-40% by weight, preferably 25% by weight) and flavor and sweetener. This layer is approximately 4 mils (100 microns) thick and is prepared at a pH of about 7.8. The innermost layer contains no tobacco and breath freshening flavors. This
10 layer is approximately 1.5 mils (37 microns) in thickness and has a pH of about 7.0.

This multilayered stick is placed in the mouth of the user where the outer layer disintegrates quickly (30-60 seconds) and provides both a pleasant sensation in the mouth and initial tobacco satisfaction. The middle layer then
15 becomes exposed, disintegrating at a much slower rate (approximately 5 minutes), providing a prolonged period of tobacco satisfaction. The innermost layer the becomes exposed, providing rapid release (approximately 30 seconds) of breath freshening flavors.

20 **Holding Devices.** Various types and forms of tobacco can be blended with food grade ingredients; attached to a holding device (e.g., a stick, a toothpick, a tobacco stem, a loop, a curved stick, an ergonomically shaped stick, a tube, or any other solid shape); dried or cooled to a solid form, if necessary, and then placed in the mouth to obtain tobacco satisfaction. During
25 use, the tobacco portion may completely disintegrate and be consumed. In other forms, the tobacco portion may remain intact and, after obtaining tobacco satisfaction, it may be discarded along with the stick or holding device. Any of the compositions described herein may be adhered to a stick or other holding device.

The tobacco used could be any type or form of the composition, e.g., tobaccos used in moist smokeless tobacco products including leaf, long cut, fine cut, and powders. Tobacco content can vary from 1% to 95% but is typically 20% to 40% based on dry weight of the product.

5 Holding devices may be formed from edible, water soluble materials but are typically formed from nonsoluble materials such as wood, paper, plastic, metal, or composite products. The shape can be of any dimension that can be easily handled and placed wholly or partially in the mouth. The tobacco
10 containing mixtures can be adhered to the holding device using any of a broad range of fabricating equipment well known in the food industry, e.g., pressing, molding, coating, depositing with a confection depositor, melting, wrapping, dipping/gelation, and similar processes and equipment.

These compositions may take the form of:

15 A tobacco containing mixture formed into a shape and adhered to one end of a holding device, thereby leaving the opposite end exposed for holding in the hand.

A tobacco containing mixture coated on to a holding device covering nearly all of the holding device but leaving sufficient area exposed to provide a holding area for the hand.

20 A tobacco containing mixture can be used to completely coat a holding device, e.g., a toothpick. The coated product can be held in the hand while one end is placed in the mouth or the entire coated product can be placed in the mouth to obtain tobacco satisfaction. After use, the insoluble holding device is discarded.

25 The thickness of the tobacco mixture applied to the holding device will vary from a minimal layer necessary to provide tobacco satisfaction to a maximum size which can still be conveniently place in the mouth. Typically, the minimum coating thickness would be two (2) mils (0.002 inches) while the maximum size would be a shape approximately one (1) inch in diameter.

In other embodiments, an outer wrap of porous material (paper, film, nonwoven material, or other material as described herein) contains a tobacco mixture and adheres the mass to a holding device.

5 Example 62. Coatings

A holding device is dipped into the tobacco containing solution and then removed and partially dried in a laboratory oven for 10 minutes at 75 °C. This process is repeated until the holding device has a coating of the desired thickness. Each dipping procedure adds approximately five (5) mils (0.005
10 inches) of coating thickness to the holding device. The holding device can be coated only at one end, or it can be coated completely leaving only a small exposed holding area at one end. In another example, the holding device can be fully immersed in the tobacco containing solution so the holding device is completely coated. In yet another embodiment, the holding device can be
15 enrobed by placing it on a porous tray or screen and pouring the solution over the holding device thereby completely coating it. In yet another embodiment, the coated holding device is dried to reduce the water content to less than 20% by weight and more typically to about 5% by weight.

Exemplary tobacco containing solutions are described in Table 1.3 and
20 Example 2.

Example 63. Wrapping

A holding device can be partially or wholly wrapped with a film as described herein, e.g., Table 1.3 and Examples 2, 3, 4, and 6. The film can be
25 repeatedly wrapped around the stick while applying a thin stream of water or other edible adhesive to the inner surface of the film thereby causing the layers of film to adhere firmly and to form a solid, tobacco containing shape around the stick. By utilizing non-tobacco containing films described herein, e.g., in

Examples 3 and 4, it is possible to create a tobacco coating or wrap on the holding device whereby the outer layer(s) or wrap(s) are colored and flavored but do not contain tobacco.

5 Example 64. Pouch on a Stick

A portion of a white, paper-like film, e.g., as described in Example 16, can be placed on a heat sealing die: a portion of a mixture of tobacco, binder, and flavoring materials can be placed on the paper; a stick or toothpick can be partially inserted into the tobacco mixture; another equal sized portion of the
10 white, paper-like film can be placed on top of the tobacco mixture; and the heat sealing die is closed to create a seal or weld around the perimeter of the film simultaneously enclosing the tobacco mixture to form a pouch and sealing the pouch to the holding device.

The tobacco containing pouch can be placed in the mouth where it
15 slowly disintegrates. The holding device of this example is used as a handle to place and manipulate the tobacco portion during use. After use, the holding device is removed from the mouth and discarded.

Example 65. Tabs

20 A holding device can be inserted into a tab, as described herein, before it completely dries or solidifies. Exemplary tabs are described in Example 37 and Example 38.

Example 66. Shaped Parts

25 Shaped part tobacco compositions, as described herein, may also be formed around a holding device using methods known in the art, e.g., extrusion, compression molding, injection molding, impact molding, and foam molding. Such shaped parts may be based on water soluble or thermoplastic formats. Exemplary shaped parts are described in Examples 39-42 and 46.

The holding device can also be inserted prior to the molding or prior to the setting up or drying of the shaped parts.

Example 67. Gels

- 5 A holding device can be inserted into a gel, as described herein in Examples 48-51, before it completely dries or solidifies.

Example 68. Coated Stems

- 10 Expanded or puffed stems of the tobacco plant are coated with solutions, dispersions, suspensions, or gels comprising tobacco, binder, flavoring agents and other processing aids; the coatings are subsequently dried through the application of heat to produce compositions that can be placed, at least partially, in the mouth. After use, the product is removed from the mouth and discarded.

- 15 Expanded or puffed stems of the tobacco plant typically provide very low tobacco satisfaction and exhibit harsh tastes when placed in the mouth. The subject coatings may improve tobacco satisfaction while adding flavors, sweeteners, flavor masking, and bitterness blocking additives and other ingredients to improve the organoleptic experience when using expanded or
20 puffed stems.

- A coating solution was prepared using the formula shown in Table 68.1. The resulting solution was adjusted to a solids content of 15% and a viscosity of 5,000 centipoise measured on a Brookfield viscometer at 70 °C. Tobacco stems were immersed in the solution for 10 seconds; they were removed and
25 placed on a waxed paper lined tray; and dried for 20 minutes in a laboratory oven at a temperature of 75 °C. The dried stems were uniformly coated with the solution at a thickness of four mils (0.004 inches).

Table 68.1

Hydroxypropyl cellulose	4.13
Methyl hydroxypropyl cellulose	2.25
Starch (B-792 from GPC)	3.00
Revel XM (tobacco)	4.36
Glycerin	0.79
Propylene glycol	0.70
PEG-400	0.87
Cinnamon flavor	0.87
Other flavors	0.78
Processing aids	0.79
Water	81.46
Total	100

D. Modifications

Any tobacco composition described herein may be modified in various ways. For example, a composition may be coated in single or multiple layers. Such coatings are employed, e.g., for handling, disintegration rate, taste, and color. Exemplary coatings include HPMC or HPMC/HPC blends. Coatings or decorative patterns may be applied to the surface of the film using processes known in the art, e.g., spraying, brushing, roll coating, doctor bar casting, slot coating, extrusion coating, hot melt deposition, depositing particles or flakes, and other typical methods. Coatings may be matte or glossy. A coating may contain a color, flavor, sweetener, or flavor masking agent, as described herein. The color, flavor, sweetener, or flavor masking agent in the coating may be same or different as the underlying composition. In addition, multiple coatings may also contain the same or different color, flavor, sweetener, or flavor masking agent. The coating may also disintegrate at a different rate than the underlying composition. For example, a coating may disintegrate faster than the underlying composition to provide a burst of flavor or other organoleptic

components. An orally disintegrable coating may also be placed on a composition that does not disintegrate orally. A coating that does not disintegrate orally may be placed on a composition that disintegrates orally, and such a coating may be removed, e.g., by chewing. Coatings may also be employed to prevent evaporation of volatile components in a composition and to prevent mechanical maceration of a composition prior to use. A coating may also contain tobacco.

Patterns may also be printed on the surfaces of compositions. Printing patterns also encompass dusting or sprinkling compounds on the surface of a composition. The pattern may be random or in a design, e.g., a logo. All printing processes known in the art, e.g., offset, flexographic, gravure, ink jet, laser, screen printing, and other typical methods may be used. The printed pattern may or may not contain a color, flavor, sweetener, or flavor masking agent, as described herein. The color, flavor, sweetener, or flavor masking agent in the pattern may be same as or different from the underlying composition. In addition, multiple patterns may also contain the same or different color, flavor, sweetener, or flavor masking agent. The printed pattern may also contain tobacco, e.g., up to 1-99%, preferably 10-50%. Such a pattern may contain more tobacco, percentage-wise or in an absolute sense, than the underlying composition.

Flakes may also be added to compositions described herein. Flakes may be mixed into the composition, may be placed within a void in the composition, or may be placed on the surface, e.g., and adhered by a coating. Flakes may or may not contain a color, flavor, sweetener, or flavor masking agent, as described herein. The color, flavor, sweetener, or flavor masking agent in the flakes may be same or different as the underlying composition. In addition, multiple flakes may also contain the same or different color, flavor, sweetener, or flavor masking agent. Flakes may also contain tobacco, e.g., up to 99%,

preferably up to 50%. Flakes may be made by standard film forming technology as described herein. Flakes may contain more tobacco, percentage-wise or in an absolute sense, than the underlying composition.

Once the printed, coated, or decorated film has been prepared, an additional layer of film may be applied to cover, protect and seal the printed, coated or decorated surface.

Compositions of the invention may be shaped in various forms, e.g., plants and geometric shapes (e.g., round, square, rectangular, triangular, oval, octagonal, and the like). In addition, compositions may contain a pattern in relief (positive or negative) on the surface. Such a pattern may be a design, such as a logo.

Composite compositions, i.e., compositions including two or more of the different types of products described herein, are also contemplated by the invention. For example, a shaped part may contain regions of gel compositions, e.g., having a variety of flavors. In another example, a tab may be surrounded by a gel. Composite compositions may also have different rates of disintegration.

E. Packaging

Individual compositions will be packaged as appropriate for the contents of the composition. Preferably, the compositions are stored in a waterproof case and are stable between 40 and 120 °F. Compositions are typically dry, flexible, and non-adhesive while in storage. Alternatively, compositions may be packaged using non-stick barriers, e.g., plastic film or paper, between servings. Compositions may also be provided in a bulk form, from which individual servings are separated.

In another embodiment, the package is water impermeable and water insoluble, and tobacco, e.g., in liquid, slurry, or flowable gel form, is disposed within the package, e.g., a squeezable plastic package, a bellows, or a spray bottle, and is capable of being dispensed into the mouth from the package. The

bellows may be compressed for oral use. Solutions or slurries are prepared for use in a plastic bellows container or other similar consumer packaging containers wherein the liquid is injected into the mouth by squeezing the package. Thixotropic polymers are combined with tobacco and other
5 ingredients to prepare higher viscosity solutions suitable for use in other containers. Tobacco particles can be of greater size, but must still be small enough to pass through the orifice of the container. For spray bottles, a stable tobacco slurry is contained in the bottle; tobacco particles are sized to be able to pass through a spray nozzle without blocking the orifice; and the tobacco
10 slurry is sprayed directly in the oral cavity. Liquid sprays are prepared by dissolving a thixotropic polymer such as xanthan, gellan or dextran in water and suspending tobacco particles in a low viscosity (e.g., <50 centipoise) solution. Other compounds, such as flavor, sweetener and dispersant, can be added to the solution. The tobacco particles are ground to a particle size (e.g.,
15 <80 microns) to permit the homogeneous solution to pass through the orifice of a spray bottle. Other packages may be otherwise squeezed or used to expel the tobacco into the oral cavity.

F. Solutions

20 The following tobacco solutions may be included in any composition described herein.

Example 69. Sprayable Solution

A solution is prepared by mixing 0.2 grams of xanthan (Kelzan from
25 C.P. Kelco) in 78.6 grams of cool water with vigorous mixing for 30 minutes. To this solution is added 20 grams of finely ground tobacco, 0.2 grams of sucralose, and 2 grams of cinnamon flavor while continuing to mix vigorously. The solution viscosity is adjusted with water to a viscosity of 50 centipoise.

Example 70. Thick Solution

A solution is prepared by mixing 1 gram of xanthan (Kelzan from C. P. Kelco) with 76.8 grams of cool water while mixing vigorously for 30 minutes. To this is added 20 grams of fine tobacco, 0.2 grams of sucralose and 2 grams of cinnamon flavor while continuing to mix vigorously. Solution viscosity is 1,500 centipoise.

Example 71. Paste

A paste is prepared by adding 2 grams of a medium viscosity carboxymethyl cellulose (CMC 7MF from Hercules) to a mixture of 35.8 grams of cool water and 40 grams of glycerine with vigorous mixing for 30 minutes. To this mixture is added 20 grams of fine tobacco powder, 0.2 grams of sucralose, and 2 grams of cinnamon flavor. A thick paste is prepared which is highly shear sensitive. This paste can be introduced to a tube or other squeezable package where the shear force from squeezing reduces the viscosity to permit flow of the paste.

OTHER EMBODIMENTS

The description of the specific embodiments of the invention is presented for the purposes of illustration. It is not intended to be exhaustive nor to limit the scope of the invention to the specific forms described herein. Although the invention has been described with reference to several embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims. All patents, patent applications, and publications referenced herein are hereby incorporated by reference.

Other embodiments are within the claims.

What is claimed is:

CLAIMS

1. A composition comprising tobacco and an insoluble format, wherein said format partially coats said tobacco.
2. The composition of claim 1, wherein the ratio of tobacco to format is 99:1 to 50:50.
3. The composition of claim 1, wherein said format is shaped as a porous, rigid structure.
4. A composition comprising tobacco, a format, and a holding device, wherein said composition is disposed on said holding device.
5. The composition of claim 4, wherein said holding device is a toothpick.
6. The composition of claim 5, wherein said toothpick is substantially entirely enrobed by a coating comprising said tobacco and format.
7. The composition of claim 4, wherein said holding device comprises a tobacco stem.
8. The composition of claim 4, wherein said tobacco and format are formulated as a tab, gel, shaped part, or film.
9. The composition of claim 4, wherein said tobacco and format are disposed in an insoluble matrix which is attached to said holding device.
10. The composition of claim 4, wherein said format is formulated as a film and said tobacco is disposed within a pouch formed by said film being attached to said holding device.

11. The composition of claim 10, wherein said film is a porous, water-insoluble film.
12. The composition of claim 10, wherein said film disintegrates in the mouth.
13. The composition of claim 4, wherein said holding device is partially inserted into a combination of said tobacco and format.
14. A method of manufacturing a tobacco composition comprising attaching a holding device to a tobacco composition comprising tobacco and a format.
15. The method of claim 14, wherein said composition is formulated as a tab, gel, shaped part, or film.
16. The method of claim 14, wherein said holding device is a toothpick.
17. The method of claim 14, wherein said holding device comprises a tobacco stem.
18. The method of claim 14, wherein said holding device is attached by coating said composition on said holding device.
19. The method of claim 14, wherein said holding device is inserted into said tobacco composition.
20. The method of claim 14, wherein said composition comprises a film, said attaching forms a pouch of said film, and said tobacco is disposed within said pouch.

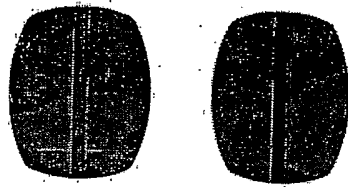
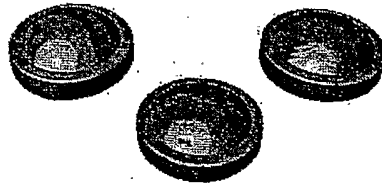


Figure 1

A



B



Figure 2

A



B



Figure 3

A

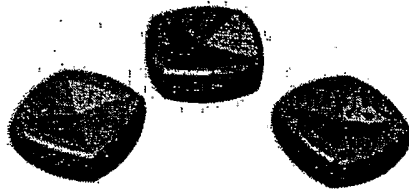


B



Figure 4

A



B



Figure 5

A



B

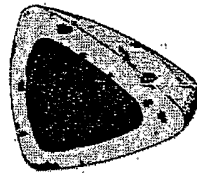


Figure 6

A

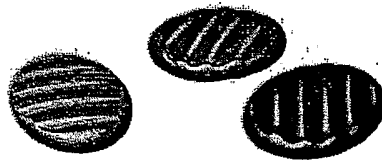


B



Figure 7

A

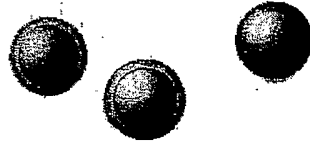


B



Figure 8

A

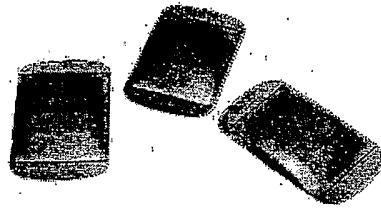


B



Figure 9

A

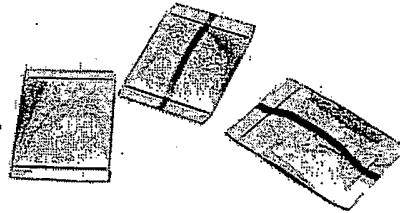


B



Figure 10

A

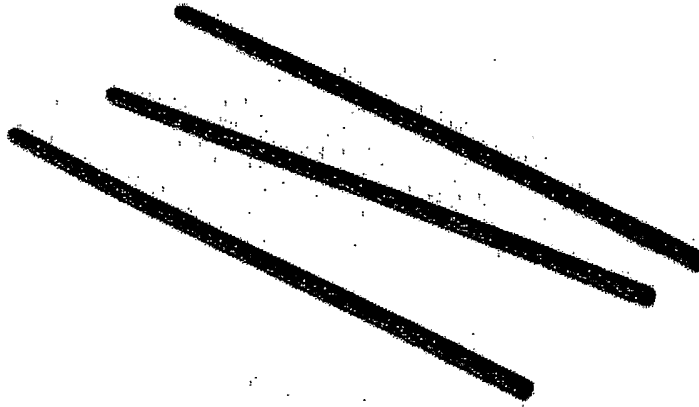


B



Figure 11

A

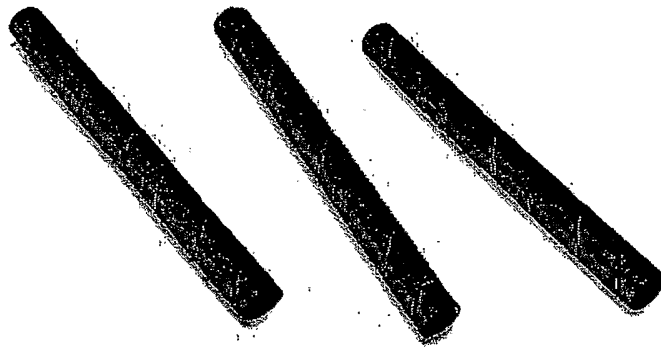


B



Figure 12

A

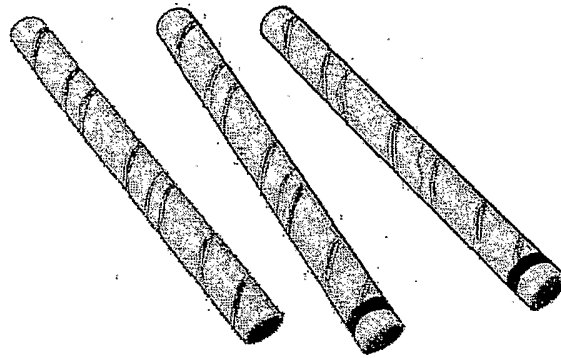


B



Figure 13

A



B



Figure 14