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(54) **COMPOSITION FOR A TOBACCO-FREE CHEW WITH LIQUID SYNTHETIC NICOTINE**

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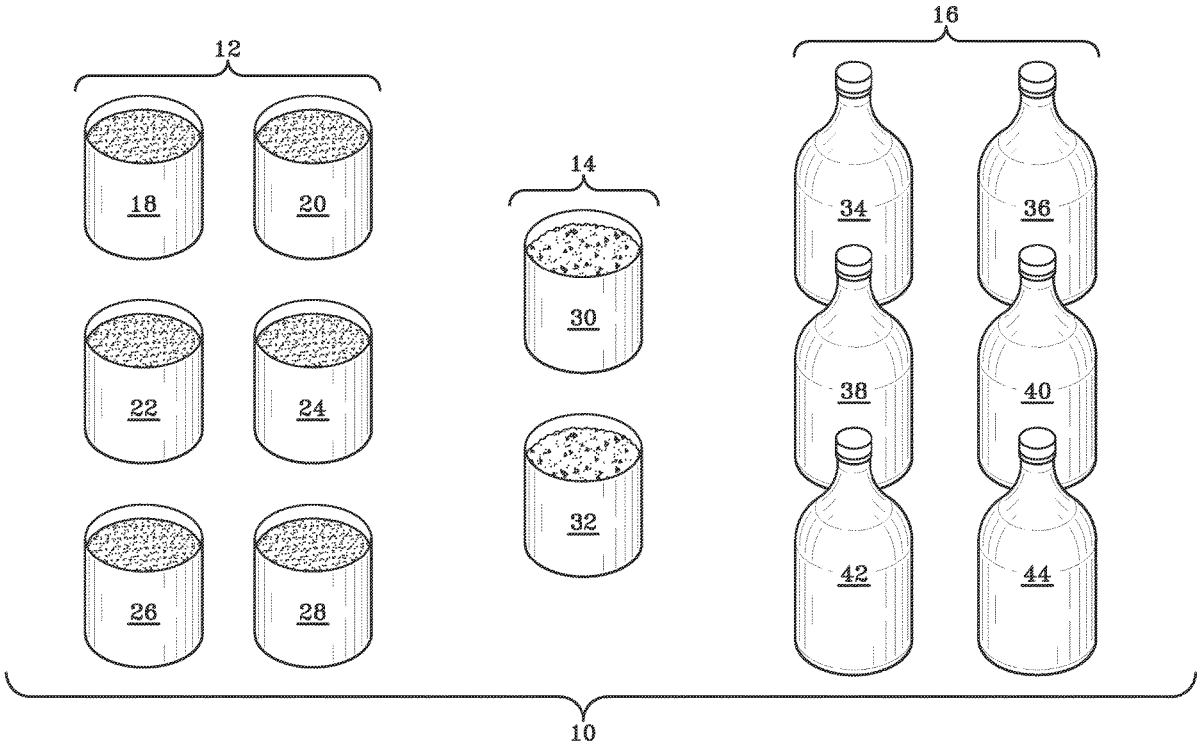
(57) **ABSTRACT**

Exemplary embodiments contained herein relate to smokeless products containing one or more non-tobacco plant materials and methods of manufacture thereof. Exemplary embodiments are related to the method of manufacture of various chew products containing non-tobacco ingredients including plant material and a starch, a sweetener, natural and artificial flavors, a pH adjuster, solvent, salt, and liquid synthetic nicotine and methods of manufacture thereof. The liquid synthetic nicotine is provided at greater volumes compared to when liquid tobacco-derived nicotine is used due to the presence of both R nicotine isomers and S nicotine isomers present in the liquid synthetic nicotine.



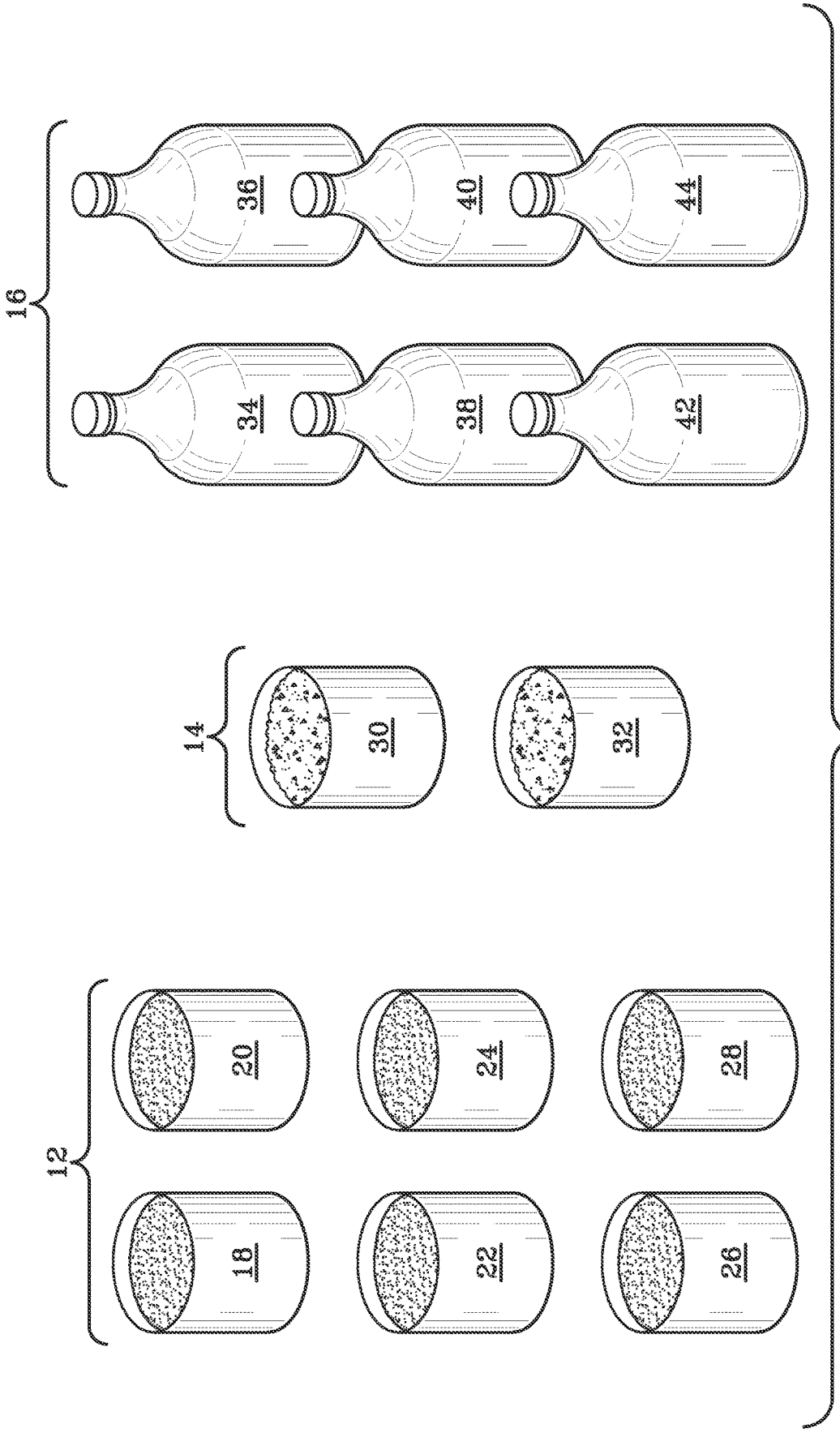


FIG. 1

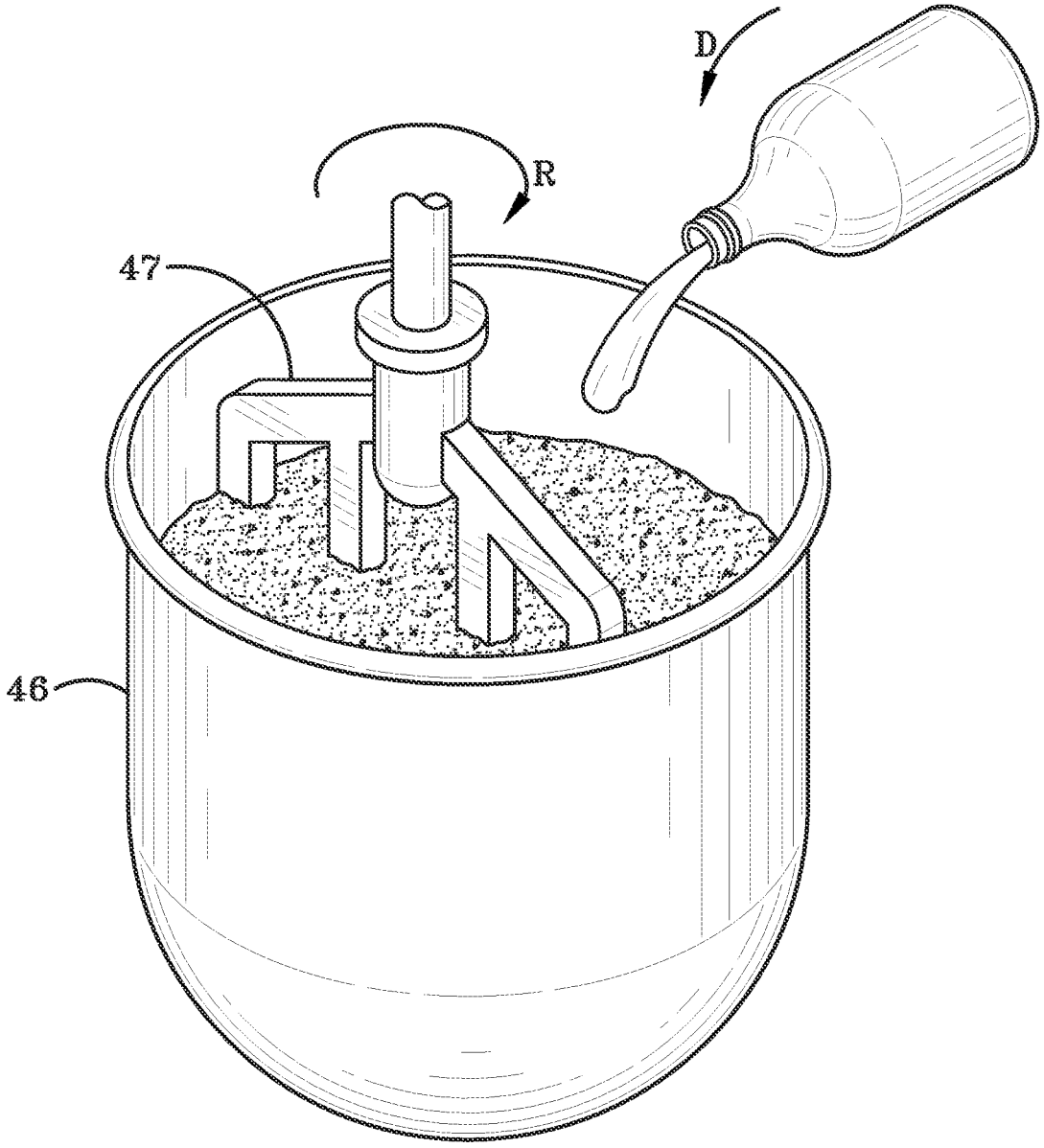


FIG.2

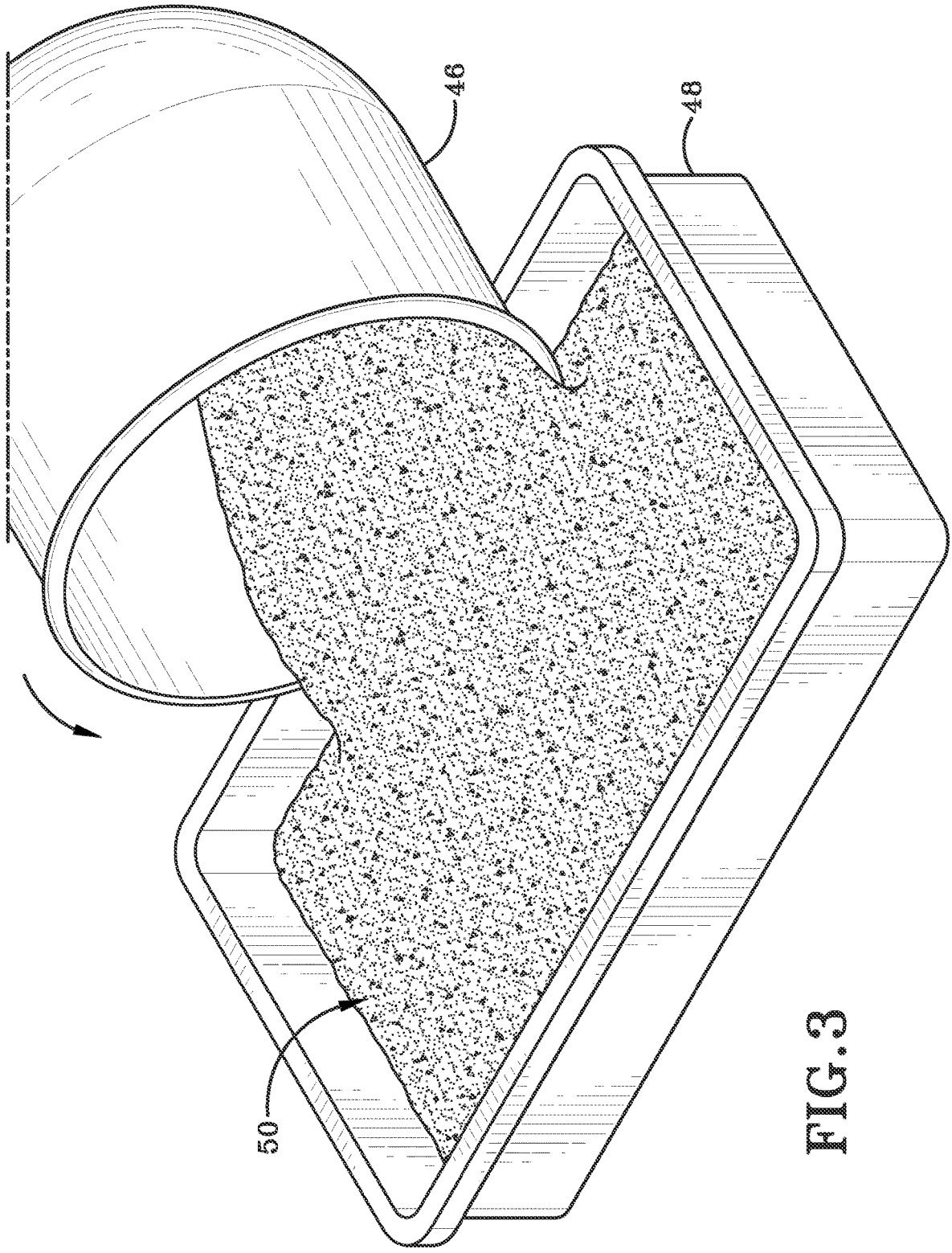


FIG.3

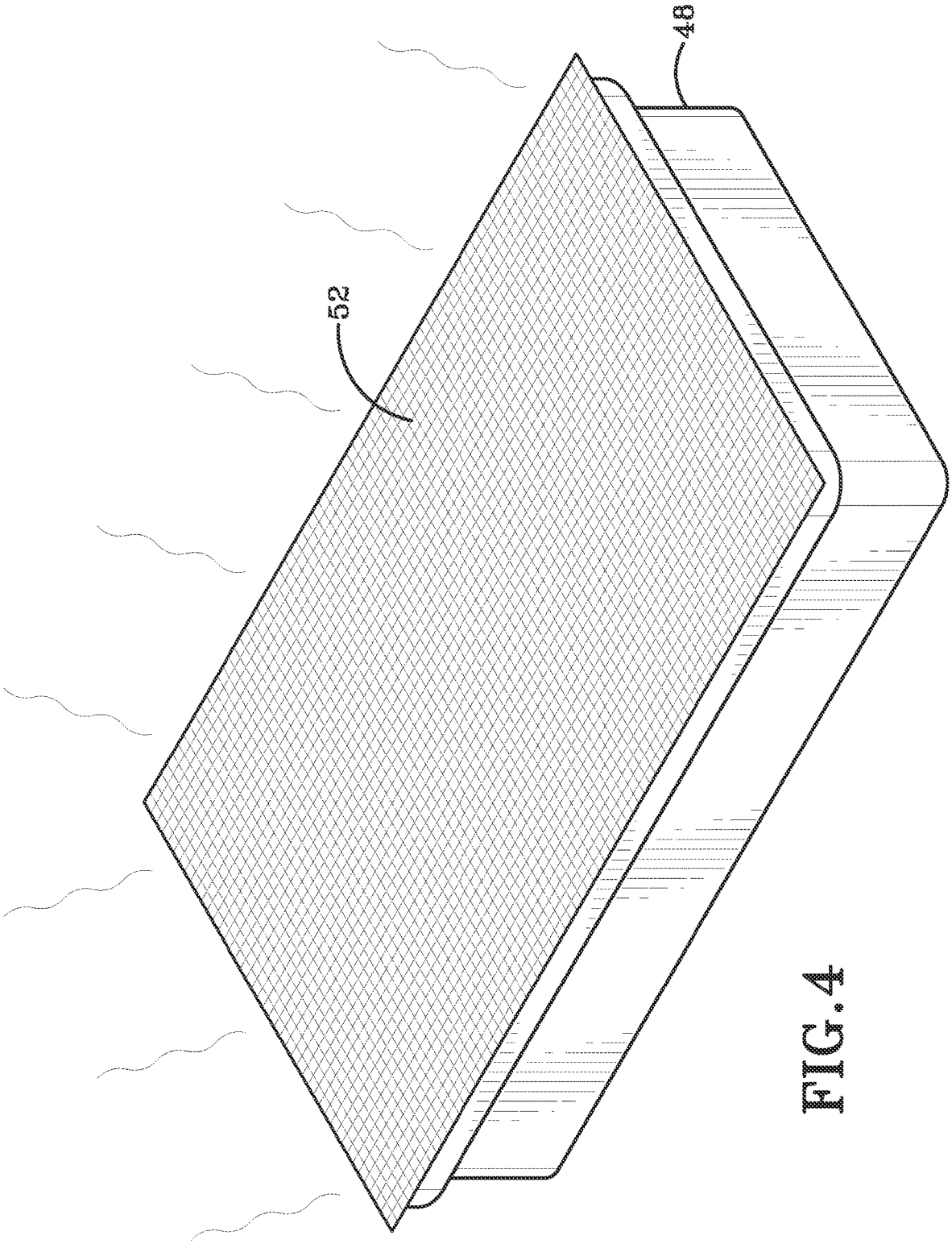
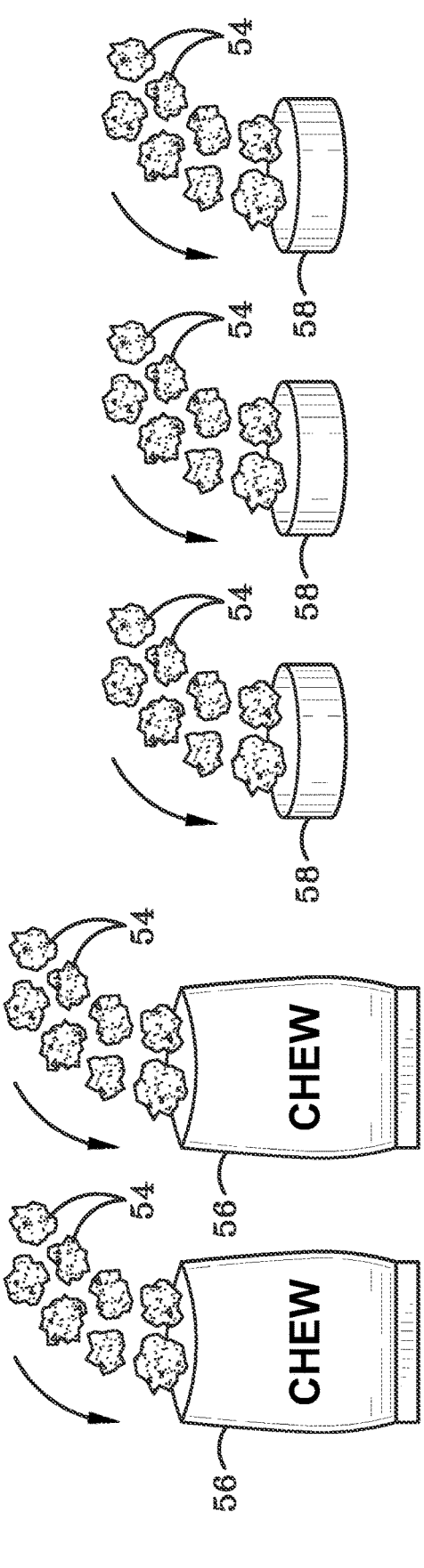


FIG. 4


54
58
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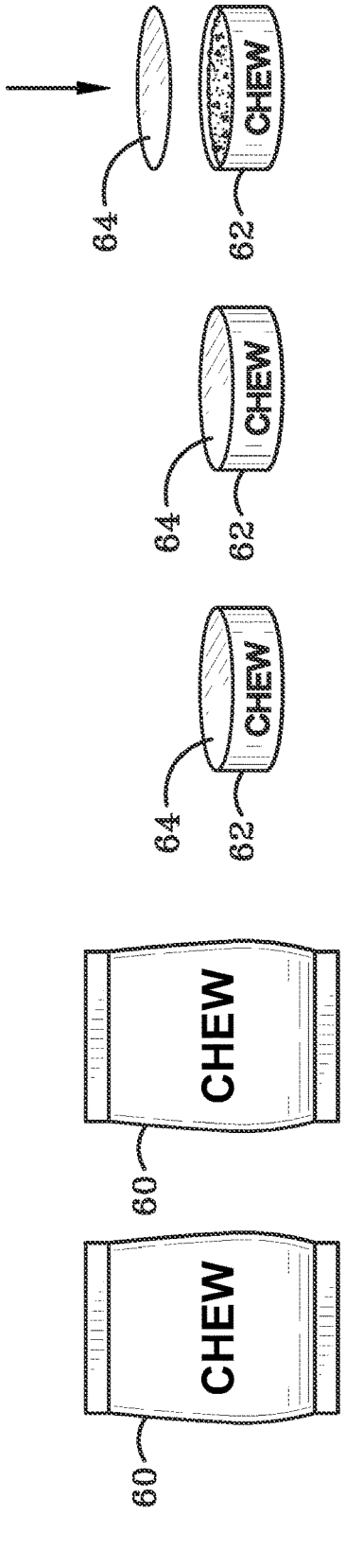
54
CHEW
56
54
CHEW
56

FIG.5A


64
62
CHEW
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62
CHEW
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62
CHEW
60
CHEW
60
CHEW

FIG.5B

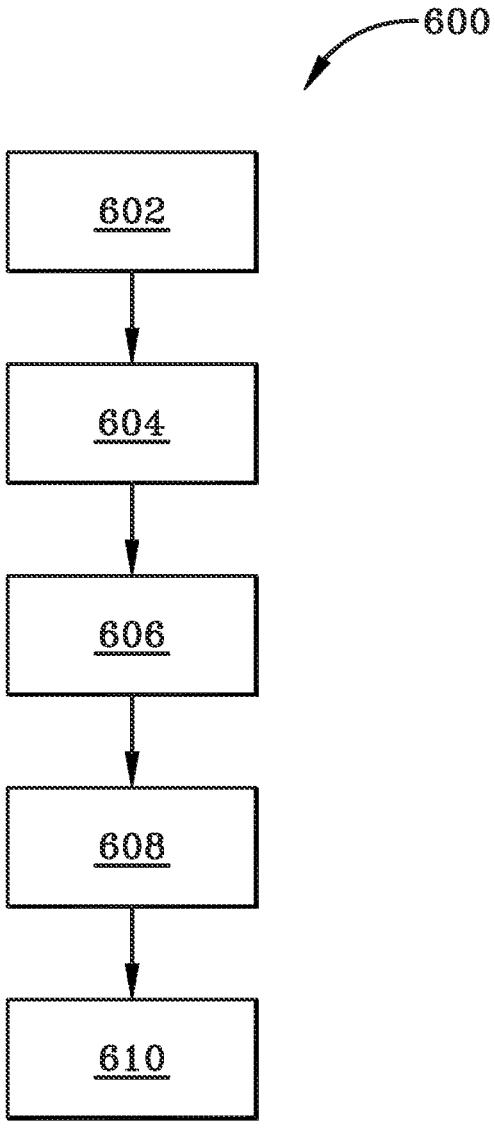
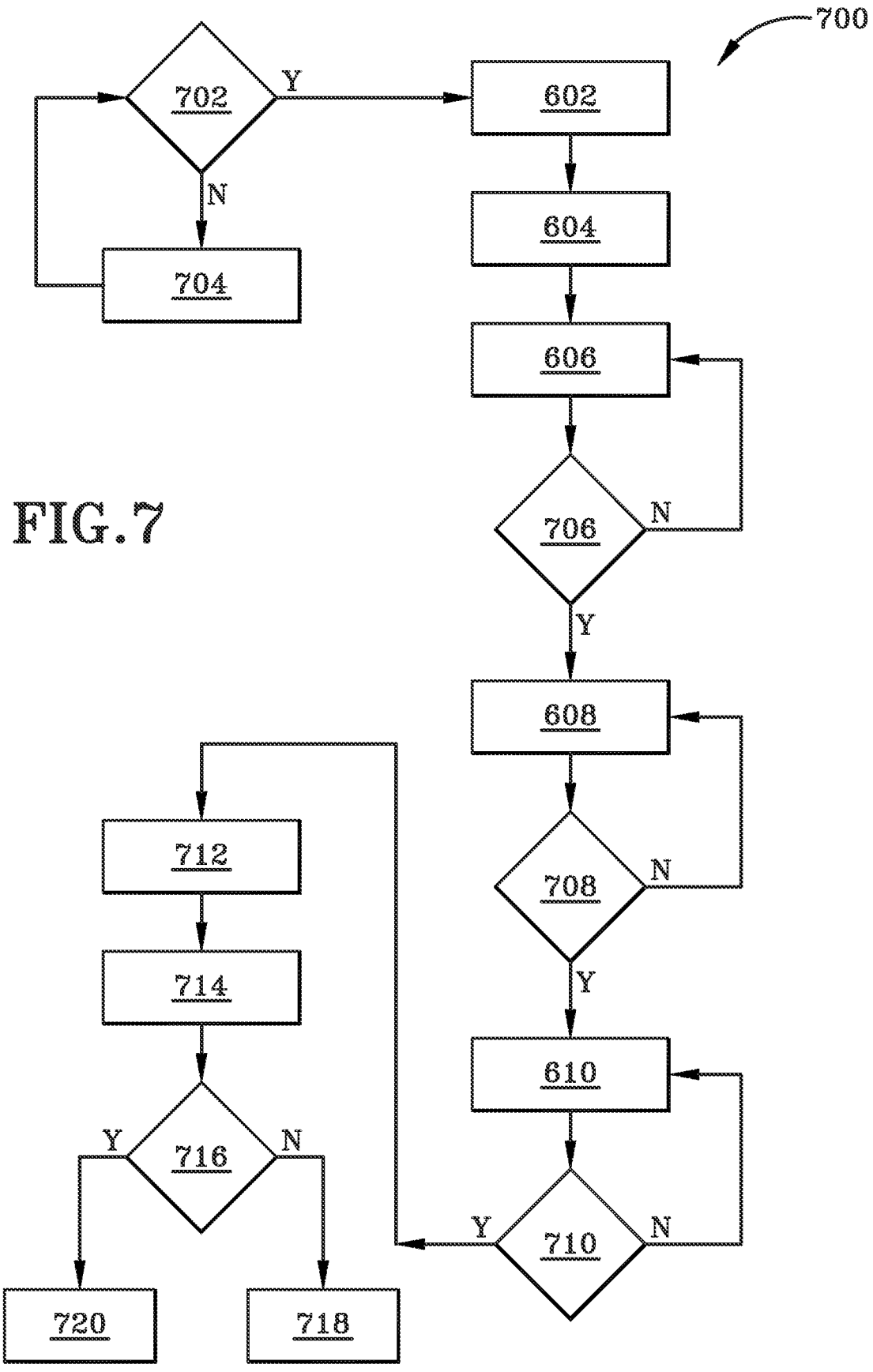


FIG.6


700
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Y
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718

FIG. 7

COMPOSITION FOR A TOBACCO-FREE CHEW WITH LIQUID SYNTHETIC NICOTINE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. patent application Ser. No. 16/180,417, filed Nov. 5, 2018; the disclosures of which is entirely incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to a tobacco-free chew product having liquid synthetic nicotine and methods of manufacturing the same. More particularly, the present disclosure relates to a tobacco-free chew product containing plant materials and flavorants and methods of manufacturing the same. Specifically, the present disclosure relates to non-tobacco ingredient plant ingredient, liquid synthetic nicotine, starch, a sweetener, a flavorant, a pH adjuster, solvent, and salt and methods of manufacturing the same.

BACKGROUND

[0003] In recent years, the harmful effects of tobacco use has been recognized by multiple campaigns both privately funded by various health groups and by governmental agencies. These campaigns have done well to communicate various information about the adverse health effects related to the use of tobacco products. Many of these programs are directed to attempts to reduce the smoking incidence within the population.

[0004] Tobacco smoking alone has far reaching impacts on health. It is currently estimated that there are 3-4 million deaths per year around the world directly attributable to tobacco smoking and tobacco smoking related diseases. In a 1988 report entitled *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, it was estimated that approximately 300,000 deaths each year are caused as a result of cigarette smoking in the US alone. Smoking is internationally recognized as a major cause to health problems throughout the world. Tobacco use costs $300 billion a year in the United States. Currently, 36.5 million adults continue to smoke.

[0005] However, quitting using tobacco is extremely difficult. In fact, the World Health Organization has in its International Classification of Disorders a diagnosis called Tobacco Dependence. One primary reason individuals have trouble giving up tobacco products centers around nicotine. Nicotine is an organic compound and is the principal alkaloid of tobacco. Nicotine is the chief addictive ingredient in the tobacco used in cigarettes, cigars, snuff, chew and the like. Nicotine addicts characteristically display a strong tendency to relapse after having successfully stopped using tobacco for a time. Nicotine is the world's second most used drug, after caffeine from coffee and tea.

[0006] The administration of nicotine can give satisfaction and the usual method is by smoking. When smoking a cigarette or other tobacco containing product, nicotine is quickly absorbed into the smoker's blood and reaches the brain within around ten seconds after inhalation. The quick uptake of nicotine gives the consumer a rapid satisfaction, or kick. The satisfaction, then, lasts during the smoking time of the cigarette and for a period of time thereafter.

[0007] However, tobacco smoke has a lot of dangerous substances that are formed during the combustion of tobacco, such as carbon monoxide, tar products, aldehydes, and hydrocyanic acid. Chewing tobacco comes with its own set of issues as well, including use as a risk factor for the development of oral cancers and precancers. Additionally, using chewing tobacco can include other health risks including, but not limited to gum disease, tooth decay, tooth loss, links to various other cancers and cardiovascular disease.

[0008] As a result, there has been a push for tobacco alternative products and methods. Recently "electronic cigarettes", "e-cigarettes" or "personal vaporizers", are becoming increasingly popular. These are often names for a personal vaporizer or vaporizer pen, which is a device that heats and vaporizes a liquid material such as a liquid tobacco or an herbal extraction product without causing combustion. These devices may be used by various people to simulate tobacco smoking, including current or past smokers of tobacco cigarettes and individuals who never were smokers of tobacco cigarettes.

SUMMARY

[0009] However, using tobacco and tobacco derived products has health hazards and it is therefore desirable to formulate an alternative way of administering nicotine in a pleasurable manner that can be used to facilitate withdrawal from tobacco and/or used as a replacement for the use of tobacco. Therefore, it is prudent to develop a product free of tobacco, yet still capable of delivering nicotine in an improved manner. This is accomplished through the usage of liquid synthetic nicotine (i.e., nicotine that is synthesized in a laboratory and not derived from tobacco).

[0010] Exemplary embodiments relate to compositions, such as tobacco-free chew, containing a base material free of tobacco plant materials as well as methods of manufacture related thereto. Additionally, these exemplary compositions include liquid synthetic nicotine that is not derived from tobacco.

[0011] This exemplary embodiment or another exemplary embodiment may further comprise, a non-tobacco leaf material, a flavorant, and synthetic nicotine. This exemplary embodiment or another exemplary embodiment may further comprise, a diluent, wherein the diluent is operative to dilute the synthetic nicotine to a lower amount. This exemplary embodiment or another exemplary embodiment may further comprise a composition has a pH greater than 7; more particularly, the composition has a pH greater than 7.5. One embodiment provides a preferred pH at 8.6. This exemplary embodiment or another exemplary embodiment may further comprise, a composition wherein the amount of free nicotine after being exposed to a diluent and an alkaline pH would equal that of a similar undiluted concentration.

[0012] In an exemplary embodiment a composition of tobacco-free chew comprises mint leaves, ground arrowroot, water, natural flavors, artificial flavors, colors and/or dyes, propylene glycol and nicotine as well as methods of manufacture related thereto.

[0013] A further embodiment provides for a composition of tobacco-free chew comprises mint leaves, ground arrowroot, water, natural flavors, artificial flavors, colors and/or dyes, propylene glycol and free of any nicotine as methods of manufacture related thereto.

[0014] In one aspect, the present disclosure may provide a composition containing: non-tobacco ingredient plant ingredient, starch, a sweetener, a flavorant, a pH adjuster, solvent, and salt. This exemplary embodiment or another exemplary embodiment may further provide where the sweetener comprises molasses. This exemplary embodiment or another exemplary embodiment may further provide where the pH adjuster includes at least one of baking soda and ammonium salt. This exemplary embodiment or another exemplary embodiment may further provide where the non-tobacco plant ingredient comprises shredded spearmint leaves. This exemplary embodiment or another exemplary embodiment may further provide where the starch component is derived from arrow root. This exemplary embodiment or another exemplary embodiment may further provide where a weight percentage of the non-tobacco plant ingredient and starch is in a range of about 20% to about 40% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide where a weight percentage of the non-tobacco plant ingredient and starch is in a range from about 37% to about 30% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of the non-tobacco plant ingredient and starch is in a range from about 27% to about 30% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of sweetener is in a range from about 10% to about 35% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of sweetener is in a range from about 18% to about 27% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of flavorant is in a range from about 10% to about 35% of the total composition This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of flavorant is in a range from about 17% to about 26% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide wherein the flavorant comprises natural and artificial flavors. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of pH adjuster is in a range from about 0.1% to about 3% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of pH adjuster is in a range from about 0.5% to about 1.0% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of solvent, wherein the solvent is water and is in a range of about 15% to about 30% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of solvent is in a range of about 20% to about 24% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of salt is in a range of about 0.5% to about 3% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of salt is about 0.5-1% of the total composition

[0015] This exemplary embodiment or another exemplary embodiment may further comprise liquid synthetic nicotine, wherein the liquid synthetic nicotine is diluted at a general ratio of vegetable glycerin to liquid synthetic nicotine from 2:1 to 4:1 more particularly, glycerin to liquid synthetic nicotine is 3:1. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of liquid synthetic nicotine is about 0.05% to about 5% of the total composition. This exemplary embodiment or another exemplary embodiment may further provide a weight percentage of liquid synthetic nicotine is about 0.16% to about 0.35% of the total composition.

[0016] This exemplary embodiment or another exemplary embodiment may further provide for a plasticizer, wherein the plasticizer comprises propylene glycol and is generally at a weight percentage of plasticizer is up to about 10% of the total composition, and is more particularly at a weight percentage of plasticizer is up to about 6% of the total composition. wherein the percent weight of the plasticizer is up to about 6% of the total weight of the composition.

[0017] In another aspect, the present disclosure may provide a method of making a tobacco-free chew composition comprising: measuring ingredients, including non-tobacco ingredients including non-tobacco plant material, a starch, a sweetener, a flavorant, a pH adjuster, a solvent, and salt, adding said ingredients into a mixer, mixing said ingredients in the mixer, drying the mixed ingredients, and packaging the ingredients into a package. This exemplary embodiment or another exemplary embodiment may further provide subsequent to packaging, diluting the synthetic nicotine with a diluent, wherein a ratio of the diluent to the synthetic nicotine in a range from about 2:1 to about 4:1. This exemplary embodiment or another exemplary embodiment may further provide where adding of the ingredients incudes: adding half of the wet ingredients to the mixer; adding half of the dry ingredients to the mixer; adding the rest of the wet ingredients to the mixer; and adding the rest of the dry ingredients to the mixer. This exemplary embodiment or another exemplary embodiment may further provide dyeing the starch material with a dye, wherein dyeing the starch material includes weighing the starch material, calculating out a brown colored dye at a concentration of about 1.75 oz per pound of starch material, adding the dye to the starch material and mixing the starch material in a mixer. This exemplary embodiment or another exemplary embodiment may further provide prior to drying the mixed ingredients occurs, determining if the ingredients are sufficiently mixed. This exemplary embodiment or another exemplary embodiment may further provide prior to packaging the ingredients occurs, weighing the mixed ingredients after drying to determine moisture content, determining if the mixed ingredients are at the proper moisture content, redrying the mixed ingredients if the mixed ingredients are not at the proper moisture content for an additional time, and passing the mixed ingredients on to packaging if they are sufficiently dry. This exemplary embodiment or another exemplary embodiment may further provide where packaging the ingredients includes: filling the package, weighing the package, determining proper package weight, returning the package to for more mixed ingredients to be added if the package is below proper weight, sealing the package if it is at the proper weight and subsequent to packaging, briefly storing the package. This exemplary embodiment or another exemplary embodiment may further provide subsequent to storing the package and further comprising, checking the package for any leaks, discarding the package if it has the presence of any leaks, preparing to sell the package if it is substantially free of any leaks. This exemplary embodiment or

another exemplary embodiment may further provide measuring an amount of nicotine.

[0018] Additionally, the can or tin that is packaged the non-tobacco chew composition of the present disclosure may be packaged in five-pack sleeves for retail purchase. The sleeve formed of five cans are manufactured by stacking five cans and shrink-wrapping the stacked cans together. The shrink-wrapping may occur by placing a plastic sleeve over the stacked cans and exposing the plastic sleeve to heat so it contracts to reduce its size and wrap the cans together.

[0019] In one aspect, the present disclosure may provide a composition consisting essentially of: non-tobacco plant ingredient, starch, a sweetener, a flavorant, a pH adjuster, solvent, and salt.

[0020] In another aspect, the present disclosure may provide a composition comprising a non-tobacco leaf material, a flavorant; and synthetic nicotine that is not derived from tobacco. This exemplary embodiment or another exemplary embodiment may further provide for a diluent, wherein the diluent is operative to dilute the synthetic nicotine to a lower concentration. This exemplary embodiment or another exemplary embodiment may further provide a ratio of diluent to synthetic nicotine in a range from about 2:1 to about 4:1. This exemplary embodiment or another exemplary embodiment may further provide for a ratio of diluent to synthetic nicotine is about 3:1. This exemplary embodiment or another exemplary embodiment may further provide for an amount of free nicotine in the synthetic nicotine, after being exposed to the diluent and an alkaline pH approximates a similar amount of free nicotine in an undiluted concentration at a neutral or acidic pH. This exemplary embodiment or another exemplary embodiment may further provide for a starch, a sweetener, a pH adjuster, a solvent and a salt. This exemplary embodiment or another exemplary embodiment may further provide wherein the pH adjuster includes one of baking soda and an ammonium salt. This exemplary embodiment or another exemplary embodiment may further provide for the non-tobacco leaf material comprises shredded spearmint leaves.

[0021] This exemplary embodiment or another exemplary embodiment may further provide for the composition has a pH greater than 7. This exemplary embodiment or another exemplary embodiment may further provide for the composition has a pH greater than 7.5. In one particular embodiment, it has been determined to be beneficial to maintain the pH greater than 8.0, particularly maintaining the pH around 8.6.

[0022] In yet another aspect, another embodiment of the present disclosure provides a composition comprising: a non-tobacco leaf material comprising a combination of spearmint leaves and arrowroot; a flavorant, wherein the flavorant comprises capsaicin adapted to produce a burning sensation upon contact with a tissue during chewing usage; liquid synthetic nicotine that is not derived from tobacco, wherein the liquid synthetic nicotine comprises S nicotine isomers and R nicotine isomers; a ratio of S nicotine isomers to R nicotine isomers in the liquid synthetic nicotine in a range from about 3:1 to about 1:3; the liquid synthetic nicotine having a weight that is in a range from about 0.15% to about 0.5% of the total weight of the composition; a diluent, wherein the diluent is operative to dilute the synthetic nicotine to a lower concentration, while maintaining the weight that is in the range from 0.3% to 0.5% of a total weight of the composition, and wherein a ratio of diluent to liquid synthetic nicotine is about 3:1, wherein an amount of free nicotine in the liquid synthetic nicotine, after being exposed to the diluent and an alkaline pH approximates a similar amount of free nicotine in an undiluted concentration at a neutral or acidic pH; a pH adjuster comprising at least one of baking soda and an ammonium salt, wherein the pH adjuster maintains the composition at a pH greater than 8.0; wherein the composition is adapted to be packaged in a pouch or a can and the composition adapted to deliver the liquid synthetic nicotine during chewing usage.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0023] A sample embodiment of the disclosure is set forth in the following description, is shown in the drawings and is particularly and distinctly pointed out and set forth in the appended claims. The accompanying drawings, which are fully incorporated herein and constitute a part of the specification, illustrate various examples, methods, and other example embodiments of various aspects of the disclosure. It will be appreciated that the illustrated element boundaries (e.g., boxes, groups of boxes, or other shapes) in the figures represent one example of the boundaries. One of ordinary skill in the art will appreciate that in some examples one element may be designed as multiple elements or that multiple elements may be designed as one element. In some examples, an element shown as an internal component of another element may be implemented as an external component and vice versa. Furthermore, elements may not be drawn to scale.

[0024] FIG. **1** (FIG. **1**) is a perspective view of various containers of ingredients.

[0025] FIG. **2** (FIG. **2**) is a perspective view of an exemplary mixer focused on the mixing bowl with the paddle operative to spin, as liquid ingredients are added.

[0026] FIG. **3** (FIG. **3**) is a perspective view of the mixing bowl being emptied into a tray.

[0027] FIG. **4** (FIG. **4**) is a perspective view of the tray covered with a screen, allowing for evaporation.

[0028] FIG. **5**A (FIG. **5**A) is a view of chew product being added to exemplary containers including pouches and cans.

[0029] FIG. **5**B (FIG. **5**B) is a view of exemplary sealed and packaged chew.

[0030] FIG. **6** (FIG. **6**) is a flowchart for an exemplary method.

[0031] FIG. **7** (FIG. **7**) is a flowchart for a further exemplary method.

[0032] Similar numbers refer to similar parts throughout the drawings.

DETAILED DESCRIPTION

[0033] Referring now to the figures, FIG. **1** shows containers of various ingredients **10** that are to be combined to form a composition **54** for a tobacco free chew product adapted to be retained with a user's mouth. The ingredients **10** are separated into two main categories. Dry ingredients **12** having a subset of the dry ingredients **12** as plant based ingredients **14**, and wet ingredients **16**. Dry ingredients may be comprised natural flavorants **18**, artificial flavorants **20**, pH adjusters such as an ammonium salt **22**, baking soda **24**, a salt component **26**, and a dry sweetener **28**, such as xylitol, along with of alternative plant based ingredients to tobacco including mint leaves **30** and a starch containing compound

32. The wet ingredients **16** may include a wet sweetener **34**, such as molasses, solvent **36**, liquid or emulsion based flavorants **38**, nicotine **40**, plasticizer **42**, such as propylene glycol, and a diluent **44**.

[0034] As tobacco has both texture as well as plant matter, and it is desirable to recreate the chew of tobacco with other plant matter **14**, or tobacco-alternative plant based ingredients **14**. An exemplary embodiment herein provides for the use of mint leaves **30** and a starch containing compound **32**, such as arrowroot.

[0035] An exemplary embodiment provides for the use of mint leaves **30** as a source of tobacco-alternative plant materials. As used herein "mint leaves" refers to plants of the genus *Mentha*. The genus *Mentha* includes but is not limited to those listed in the USDA, ARS, National Genetic Resources Program, Germplasm Resources Information Network—(GRIN), National Germplasm Resources Laboratory, Beltsville, Md. Examples of this genus include, but are not limited to: *Mentha aquatica, Mentha canadensis, Mentha cervina, Mentha japonica, Mentha logifolia, Mentha piperita, Mentha pulegium, Mentha spicata*, and *Mentha suaveolens*. Mint leaves may provide a source of a dry ingredient. The term "leaves" or "mint leaves" specifically excludes any corn derived product or substance. An exemplary embodiment of the chew allows for spearmint leaves to make up 15-30% of the chew. The spearmint leaves may more particularly include about 17-23% of the chew.

[0036] In exemplary embodiments, the composition includes a starch containing compound **32** as a source of tobacco-alternative plant based ingredients **14**. The starch containing compound **32** is operative to adequately simulate the consistency of chewing tobacco.

[0037] Starch is the most abundant storage carbohydrate in higher plants. Starches comprise primarily amylase and amylopectin, but the physical properties of starches and, therefore, the applications, depend on the starch composition and are unique for each botanical source. As an example, starch from different plants may comprise amylose and amylopectin in varying ratios along with a varying chain length and varying degrees of branching. Some starches further comprise additional components, such as phosphates, lipids, and/or proteins. Starches may exhibit varying levels of cross-linking between polymer chains. Further, starch can vary in average granule size, size distribution, and shape. For example, rice-derived starch is generally around 2 μm, maize-derived starch is generally around 12-30 μm, wheat-derived starch is generally around 30-45 μm, and potato-derived starch is generally around 50-100 μm.

[0038] These and other differences can significantly affect the physical properties of the starch. For example, they may impact the swellable potential of starch granules, that is how much water may be held by the starch. For example, the higher the crystallinity of the starch, the higher the swellable potential of the starch. The crystallinity of a given starch is, in turn impacted by the ratio of amylase to amylopectin. High levels of amylase typically decrease the crystallinity of a starch, and thus, decrease the swellable potential. The crystallinity is also impacted by the size and shape of starch granules, as smaller, spherical granules are typically less crystalline and thus have less swelling potential.

[0039] An exemplary embodiment uses arrowroot powder as the starch compound **32**. Raw arrowroot may be processed to a desired texture by the facility making the chew, or may be processed prior to arriving, including being modified, as discussed below. Other exemplary sources of starch compound **32** may include, but are not limited to, arrowroot, arracacha, bananas, barley, beans, breadfruit, buckwheat, canna, chestnuts, colacasia, katakuri, kamut, kudzu, malanga, millet, oats, oca, Polynesian arrowroot, sago, sorghum, sweet potato, *quinoa*, rice, rye, spelt, tapioca, taro, tobacco, triticale, water chestnuts, and yams.

[0040] In exemplary embodiments, certain starches may be modified starches. A modified starch has undergone one or more structural modifications, often designed to alter its properties. Most notably, heat stability. Other exemplary starches have been developed by genetic modifications, and are considered to be "modified" starches. Other starches are obtained from plant based material and subsequently modified. For example, modified starches can be starches that have been subjected to chemical reactions, such as esterification, etherification, oxidation, depolymerization (thinning) by acid catalysis or oxidation in the presence of base, bleaching, transglycosylation and depolymerization (e.g., dextrinization in the presence of a catalyst), cross-linking, enzyme treatment, acetylation, hydroxypropylation, and/or partial hydrolysis. Exemplary embodiments may be modified by heat treatments, such as pregelatinization, dextrinization, and/or cold water swelling processes. In other embodiments, certain modified starches may include, but are not limited to: monostarch phosphate, distarch glycerol, distarch phosphate esterified with sodium trimetaphosphate, phosphate distarch phosphate, acetylated distarch phosphate, starch acetate esterified with acetic anhydride, starch acetate esterified with vinyl acetate, acetylated distarch adipate, acetylated distarch glycerol, hydroxypropyl starch, hydroxypropyl distarch glycerol, starch sodium octenyl succinate.

[0041] An exemplary embodiment of the chew composition **54** allows for tobacco-alternative plant based ingredients **14** and starch **32** to generally include about 20-40% of the total weight of the chew composition **52**. The tobacco-alternative plant based ingredients **14** and starch **32** in the chew may more particularly include about 27-30% of the total weight of the chew.

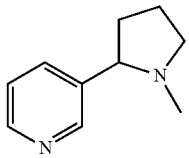
[0042] Exemplary embodiments may contain nicotine **40**. In some cases, liquid nicotine can be tobacco-derived nicotine, synthetic nicotine, or combinations thereof. Liquid nicotine can be purchased from commercial sources, whether tobacco-derived or synthetic. Liquid tobacco-derived nicotine can include one or more other tobacco organoleptic components other than nicotine. The liquid tobacco-derived nicotine can be extracted from raw tobacco and/or processed tobacco. Typically, tobacco-derived nicotine contains significantly larger portions of the S nicotine isomer but relatively little amounts of the R nicotine isomer, wherein the S nicotine isomer is the physiologically active variant.

[0043] In one particular embodiment of the present disclosure, liquid synthetic nicotine that is not derived from tobacco is the preferred nicotine source for the composition. This exemplary embodiment may be advantageous because the liquid synthetic nicotine is free of any other secondary compounds ordinarily found in tobacco derived nicotine which have been linked to disease-causing contaminants. It is possible to obtain a 100% concentrate from a synthetic nicotine supplier, namely, Next Generation Labs LLC of San Diego, Calif. The process of which to make the nicotine is described in U.S. Pat. No. 9,556,142 and is herein incorpo-

rated by reference. However, heretofore, liquid synthetic nicotine has been used for various vaping devices. Synthetic nicotine having the ratios of R nicotine isomers and S nicotine isomers (which are the physiologically active nicotine isomers) have been found to be beneficial for use in a chew composition. The liquid synthetic nicotine with the isomer ratios discussed herein are distinguishable from previous compositions formed from nicotine salts, nicotine resins (polacrilex), or nicotine bitartrate dihydrate.

[0044] In one particular embodiment, the liquid nicotine is synthetic nicotine (i.e, nicotine that is not derived from tobacco) and the liquid synthetic nicotine comprises (R,S)-nicotine. (R,S)-nicotine is a nicotine composed of both R nicotine and S nicotine isomers.

[0045] The (R,S)-nicotine has this structure:



[0046] Typically the ratio of S nicotine isomers to R nicotine isomers is a ratio in a range from about 3:1 to about 1:3. In one embodiment, the ratio range is from about 2:1 to about 1:2. In one particular embodiment, the ratio is 1:1. When the liquid synthetic nicotine is used that contains the ratio of S nicotine isomers to R nicotine isomers in the range from about 3:1 to about 1:3 (such as 1:1 in one example), the overall volume of liquid synthetic nicotine must be greater than the amount of liquid nicotine than would have been used in a composition utilizing tobacco-derived nicotine. The reason for this is because tobacco derived nicotine is formed primarily of S nicotine isomer, with relatively small amounts (typically less than 10%) of R nicotine isomer. Inasmuch as the S nicotine isomer is the physiologically active isomer, a greater volume of liquid synthetic nicotine must be used to provide the substantially same resultant physiological response to the end user as tobacco-derived nicotine.

[0047] Accordingly, in one particular embodiment, the volume of liquid synthetic nicotine used in the composition of the present disclosure would be in a range from 20% to 75% greater than the volume of liquid tobacco-derived nicotine if the liquid tobacco-derived were to be used in the composition. Various examples depicting the use of greater volumes of liquid synthetic nicotine as compared to those using liquid tobacco-derived nicotine are described in greater detail below. Namely, See Examples 1, 3, 6, 8, 11, 13, 16, and 18.

[0048] The liquid synthetic nicotine **40** may be prepared by a method of preparing (R,S)-nicotine, comprising: reacting a nicotinate ester with N-vinyl-2-pyrrolidinone in the presence of a base and a solvent to form a first mixture; combining the first mixture with a cold acid solution to form a second mixture comprising an aqueous layer; separating the aqueous layer from the second mixture; combining the separated aqueous layer with an acid to form a third mixture; combining the third mixture with a base to form a fourth mixture comprising myosamine; reducing the myosamine to nornicotine using a reducing agent; and methylating the nornicotine to yield (R,S)-nicotine. In this method of preparing the liquid synthetic nicotine, the nicotinate ester includes an alkyl group comprising an ethyl group. Further, in this method of preparing the (R,S)-nicotine, the base is a metal hydride, and the mole ratio of the metal hydride to the nicotinate ester is from about 1 to 4. The metal hydride is selected from the group consisting of lithium hydride, potassium hydride, and sodium hydride. Further, the solvent is anhydrous, and is selected from the group consisting of a dipolar aprotic amide, an ether, a polyether, an aromatic hydrocarbon, an alcohol, and combinations thereof. Further, the solvent may be selected from the group consisting of dimethylformamide, ethyl ether, tetrahydrofuran, glyme, diglyme, toluene, xylene, benzene, ethanol, methanol, propanol, and combinations thereof. The reducing agent is selected from the group consisting of a hydrogenation catalyst and a borohydride salt. The hydrogenation catalyst may be palladium on carbon.

[0049] The liquid nicotine can be pure, substantially pure, or diluted with a diluent **44** prior to combination with the tobacco-free plant material. Particularity, the synthetic nicotine may make use of a diluent **44** may be any compound operative to dilute the nicotine **40** or other additives. Exemplary diluents **43** include, but are not limited to, propolene glycol, vegetable glycerin, aqueous vegetable glycerin, distilled water, glycerol, ethylene glycol, diethylene glycol, triacetin, ethyl laurate, diethyl suberate, triethylene glycol, glycerin, ethyl vanillate, triethyl citrate, tributyrin, diethyl sebacate, benzyl phenyl acetate, benzyl benzoate, erythritol, tetraethylene glycol, ethyl stearate, dioctyl sebacate and mixtures thereof.

[0050] In exemplary embodiments, liquid nicotine **40** is generally diluted with a diluent **44** to a concentration of between 20 to 33 weight percent with vegetable glycerin, or a 2:1-4:1 ratio, prior to mixing the liquid nicotine with the remaining ingredients. In further exemplary embodiments, liquid nicotine is more particularly diluted to a concentration of between 25 weight percent with vegetable glycerin, or a 3:1 ratio prior to mixing the liquid nicotine with the remaining ingredients. In some embodiments, the chew generally includes about 0.5-5% of the total weight of the chew of nicotine **40**. The nicotine **40** more particularly includes up to about 3.5% of the total weight of the chew.

[0051] As a result of this dilution, coupled with an alkaline or basic pH, may be effective to increase the amount of 'free base' nicotine delivered to a user. This may then allow a user to experience more nicotine, even though less of an amount is used in the formulation as a whole. This will be discussed further below.

[0052] Any of the products described herein can optionally include one or more additional ingredients. For example, in some embodiments, the chew composition **54** product can include, but are not limited to, one or more solvents **36**, sweeteners **28**, **34** humectants, flavorants **18**, **20**, **38**, plasticizers **42**, pH stabilizers and pH adjustors **22**, **24**, preservatives diluents **43** and combinations thereof, such that the base or the product in its final form mimics the flavor profile and tactile experience of certain tobacco-containing products. In some embodiments, a single substance can serve as both a plasticizer **42** and a humectant, both a humectant and a flavorant **18**, **20**, **38**, both a plasticizer **42** and a flavorant **18**, **20**, **38**, a sweetener **28**, **34** and a flavorant **18**, **20**, a plasticizer **42** and a diluent **44**, or as all five, or a combination not listed for the sake of brevity. For example, molasses can serve as a humectant, sweetener **28**, **34** and a

flavorant **18**, **20**, **38**. For example, propylene glycol can serve as a plasticizer, diluent **44** and a humectant.

[0053] An exemplary embodiment of the chew composition **54** contains a solvent **36**. In exemplary embodiments, the solvent **36** is water. Water acts as a solvent of certain water soluble molecules as well as a way to dissolve other ingredients. It should be understood that water could mean any of tap water, potable water, distilled water, deionized water, spring water, bottled water or water with a specific mineral composition to improve the chew product. In additional embodiments, ethanol, denatured ethanol, or other known food-safe additives as solvents **36** or combination of solvents **36** may be used. In some embodiments, the chew generally includes about 15-30% of the total weight of the chew of solvent **36**. The solvent **36** more particularly includes about 20-24% of the total weight of the chew.

[0054] In some embodiments, the chew can include the sweetener **28**, **34**. Such sweeteners **28**, **34** are operative to make the product taste sweet and pleasant to human taste buds. A variety of synthetic and/or natural sweeteners **28**, **34** can be used as in the diluent or added separately to the tobacco-free chew. Suitable natural sweeteners include sugars, for example, monosaccharides, disaccharides, and/or polysaccharide sugars, and/or mixtures of two or more sugars. In some embodiments, a diluent can include one or more of the following: sucrose or table sugar; honey or a mixture of low molecular weight sugars not including sucrose; glucose or grape sugar or corn sugar or dextrose; molasses; corn sweetener; corn syrup or glucose syrup; fructose or fruit sugar; lactose or milk sugar; maltose, maltriose, dextrin, maltodextrin; sorghum syrup; mannitol or manna sugar; sorbitol or d-sorbite or d-sobitol; xylitol, fruit juice concentrate; and/or mixtures or blends of one or more of these ingredients. Additional embodiments may contain non-nutritive sweeteners. Suitable non-nutritive sweeteners may include, but are not limited to, stevia (mainly stevioside and rebaudioside), saccharin, aspartame, sucralose, and acesulfame potassium. In some embodiments, the chew generally includes about 10-35% of the total weight of the chew of sweetener **28**, **34**. The sweetener **28**, **34** more particularly includes about 18-27% of the total weight of the chew.

[0055] In an exemplary embodiment, the chew can include a humectant. A humectant is a substance that can be used to keep things moist, as such humectants can be hygroscopic. Suitable humectants include but are not limited to propylene glycol, hexylene glycol, butylene glycol, glyceryl triacetate, vinyl alcohol, neoagarobiose, sugar polyols (such as glycerol, sorbitol, xylitol, maltitol, mannitol, and isomalt), polymeric polyols, quillaia, alpha hydroxyl acids (e.g., lactic acid), glycerin, aloe vera gel, molasses, and honey. In some embodiments, humectants can reduce the water activity of the product. In some embodiments, the chew generally includes about 10-45% of the total weight of the chew of humectant. The humectant more particularly includes about 18-30% of the total weight of the chew.

[0056] In exemplary embodiment, flavorants **18**, **20**, **38** may be used. Flavorants **18**, **20**, **38** are as a substance that gives another substance flavor, altering the characteristics of the solute, causing it to become sweet, sour, tangy, or other flavors. Flavorants **18**, **20**, **38** can be both natural or artificial. Exemplary flavorants **18**, **20**, **38** may be selected from the following, but not limited to: licorice, wintergreen, peach, cherry and berry type flavorants, Drambuie, bourbon, scotch, whiskey, spearmint, peppermint, lavender, cinnamon, cardamon, apium graveolents, clove, cascarilla, nutmeg, sandalwood, bergamot, apricot, geranium, honey essence, rose oil, vanilla, lemon oil, orange oil, Japanese mint, cassia, caraway, cognac, jasmin, chamomile, capsaicin, menthol, ylangylang, sage, fennel, pimento, cayenne pepper, ginger, anise, coriander, coffee, mint oils from a species of the genus *Mentha*, cocoa, tobacco free latakia and combinations thereof. Synthetic flavorants can also be used. In certain embodiments, a combination of flavorants **18**, **20**, **38** can be combined to imitate a tobacco flavor without tobacco. In other embodiments the flavorants **18**, **20**, **38** may be combined in a way to mimic various fruits, such as cherry or peach. In other embodiments the flavorants **18**, **20**, **38** are operative to mimic various mint flavors. The particular combination of flavorants **18**, **20**, **38** can be selected from the flavorants **18**, **20**, **38** that are generally recognized as safe for food consumption. These flavorants **18**, **20**, **38** may be added in the form of extracts, raw materials, powder, oil, tinctures, emulsions, and will be understood to those in the arts what may be required (depending on the solubility of various flavorants in various solvents). In some embodiments, the chew generally includes about 10-35% of the total weight of the chew of flavorant **18**, **20**, **38**. The flavorant **18**, **20**, **38** more particularly includes about 17-26% of the total weight of the chew.

[0057] In certain embodiments, as a flavorant, cayenne pepper or other capsaicin containing compounds are used as a flavorant. The cayenne pepper or other capsaicin compounds are used in order to best mimic a traditional chew product that may contain fiberglass, or glass particles, as an aid to the absorption of nicotine by the user's blood. Additionally, this burn may also be created by a user's mucous membranes readily absorbing free nicotine. As certain embodiments do not use nicotine, and no embodiment uses fiberglass, it may be advantageous for consumers to get the same burn as they would from traditional chew. Therefore, cayenne pepper or other capsaicin containing compounds may be implored in order to produce a sensation of burning sensation in any tissue with which it comes into contact.

[0058] In certain exemplary embodiments, plasticizers **42** may be used. Plasticizers **42** can, in some embodiments, soften the product, promote flexibility and reduce brittleness. Suitable plasticizers **42** include but are not limited to propylene glycol, vegetable oil, glycerin, partially hydrogenated vegetable oil, esters of polycarboxylic acids with linear or branched aliphatic alcohols of moderate chain length, and medium chain triglycerides. In some embodiments, the chew generally includes up to about 10% of the total weight of the chew of plasticizer **42**. The plasticizer **42** more particularly includes up to about 6% of the total weight of the chew.

[0059] In an exemplary embodiment, a pH stabilizer or pH adjuster **22**, **24** may be implored. A pH stabilizer or pH adjuster **22**, **24** will allow the pH of the solution to be maintained over a shelf life along with changing the pH to better suit the product. Additionally, the pH stabilizer or pH adjuster **22**, **24** may adjust the solubility of other ingredients. The pH stabilizer or pH adjuster **22**, **24** may vary based on the solvents and other ingredients used in the chew. The pH stabilizer or pH adjuster **22**, **24** may also vary based on the amount of nicotine desired to be in chew. However, a wide variety of pH stabilizers and pH adjusters **22**, **24** may be

used. Examples of pH stabilizers and pH adjusters **22**, **24** that may be used in exemplary solutions include but are not limited to: citric acid, acetic acid, phosphoric acid, benzoic acid, ascorbic acid, sodium hydroxide, glycolic acid, ammonium carbonate, ammonium phosphate, ammonium chloride, sodium carbonate, sodium bicarbonate and ammonium hydroxide or mixtures thereof. In an exemplary embodiment the pH adjuster or pH stabilizer include baking soda and an ammonium salt. In some embodiments, the chew generally includes about 0.1-3% of the total weight of the chew of pH stabilizer or pH adjuster **22**, **24**. The pH stabilizer or pH adjuster **22**, **24** more particularly includes about 0.5-4% of the total weight of the chew.

[0060] Nicotine absorption from smokeless products is influenced by the pH at the cheek. In an alkaline pH (or pH>7), environment nicotine is unionized and rapidly absorbed whereas in an acidic (or pH<7), nicotine is ionized and does not cross biological membranes nearly as well. Absorption of nicotine across the membranes within it's a user's mouth is directly related to the amount of nicotine present in the unionized "free base" form. Tobacco naturally occurs in an acidic form and therefore is slow to release free-base nicotine unless buffered to alkaline levels. Similarly, the chew product implores various pH stabilizers or pH adjusters **22**, **24** to raise the pH to an alkaline level, and be operative to maintain the chew at such an alkaline level once placed into a user's mouth. In certain exemplary embodiments, the pH may be greater than 7.0. In a further exemplary embodiment, the pH may be greater than 7.5. In a further exemplary embodiment, the pH may be greater than 8.0. In a further exemplary embodiment, the pH may be greater than 8.5.

[0061] Therefore, by increasing the pH will result in a subsequent increase to the amount of free base nicotine. This may be adequately manipulated in such a way to give a user a similar effect that more nicotine is present, while in reality there is less nicotine. This may be exploited to save substantial money on nicotine costs, as more diluent **44** could be used to dilute the nicotine to desired levels.

[0062] In a further exemplary embodiment, a preservative may be used. Food preservatives that are generally utilized in food or food related products are set forth in the U.S. Food and Drug Administration GRAS list of chemicals utilized in the food industry. Exemplary preservatives include, but are not limited to: ascorbic acid, ascorbyl palmitate, benzoic acid, butylated hydroxytoluene (BHT), calcium ascorbate, EDTA, calcium sorbate, caprylic acid, dehydroacetic acid or its sodium salt, disodium ethylenebisdithiocarbamate, erythorbic acid, formaldehyde (paraformaldehyde), methylparaben (methyl-p-hydroxybenzoate), nitrates (sodium and potassium), n-octanoic (caprylic) acid, octyl gallate, potassium metabisulfite, potassium nitrate, potassium sorbate, propionic acid, propylparaben (propyl-p-hydroxybenzoate), quaternary ammonium chloride combination, silver nitrate, silver (metal), sodium ascorbate, sodium benzoate, sodium bisulfite, sodium dimethyldithiocarbamate, sodium metabisulfite, sodium nitrate, sodium nitrite, potassium nitrite, sodium phosphate (monobasic) (monosodium phosphate), sodium propionate, sodium sorbate, sorbic acid, stannous chloride, stearyl citrate, sulfating agents, sulfur dioxide, and tocopherols, or any combination thereof. In some embodiments, the chew can include up to about 2 weight percent preservative.

[0063] In a further exemplary embodiment, a salt **26** or brine solution may be implored. The brine is a solution that can include water and one or more inorganic salts, these salts may be in a brine or by themselves. Exemplary salts may NaCl, KCl NaNO, KNO, MgCl, MgSO, CaOI, or combinations thereof. In the case of NaCl, it may be in the form of kosher salt, sea salt, iodized (table) salt, canning salt, and/or pickling salt. In some embodiments, the chew generally includes about 0.5-3% of the total weight of the chew salt **26** and/or brine. The salt **26** more particularly includes about 0.5-1.0% of the total weight of the chew.

[0064] FIG. **2** refers to the ingredients that are subsequently added to a mixing bowl **46** after being measured in their appropriate proportions. The mixing bowl **44** is mixed by a paddle attachment **47** in a rotating manner as seen by arrow "R". At times it may be useful to add in additional wet ingredients **16** prior to mixing as seen by arrow "D".

[0065] An exemplary embodiment relates to a method of manufacturing a tobacco-free chew composition **54**. Ingredients are measured out and placed into a mixer and into a mixing bowl **46** or vessel of appropriate size based on batch size. The mixer is operative to rotate a paddle attachment **46** to adequately mix the ingredients. Exemplary mixers are commercial mixers made by Hobart and other companies and are well known in the art. Ingredients may be separated into wet and dry ingredients before they are added to the mixer. This separation of ingredients is desirable as if the dry ingredients are added partially first, and then the wet ingredients **16**, and then the rest of the dry ingredients **12**. Adding the ingredients in this manner, it allows the ingredients room to move and not be ejected from the mixer as the wet ingredients **16** hydrate some of the dry ingredients **12** prior to mixing. In other embodiments, it may be appropriate to add half of the dry ingredients **12**, then half of the wet ingredients **16**, the other half of dry ingredients **12** followed by the other half of wet ingredients **16**. In an alternative embodiment, the dry ingredients **12** may be split in half, wherein the first half of the dry ingredients **12** may be added to an exemplary mixer, all of the wet ingredients **16** are added, with the exception of a sweetener **28**, **34**, for example molasses. Then, the remainder of the dry ingredients **12** are added, and then topped with the sweetener **28**, **34**. Alternative embodiments include adding the wet ingredients **16** and dry ingredients **12** incrementally over a period of time at related rates.

[0066] In an exemplary embodiment, after measuring out the ingredients and adding them to a mixer, it is mixed for a time. Depending on the desired moisture content, volume of the ingredients and speed of the mixer, this could be anywhere from 10 minutes to 4 hours. In an exemplary Hobart mixer, it is mixed for 30 minutes on the lowest setting, one.

[0067] FIG. **3** refers to the ingredients that are mixed in a mixing bowl **46** subsequently transferred into a drying bin **48** after being mixed into a relatively homogeneous mixture **50**.

[0068] After the mixing is done, the batch is transferred into a drying bin **48**. A drying bin may be any container operative to evaporate moisture within an environment. An exemplary embodiment provides for a shallow tub, but any container with proper air flow and a requisite high surface area would be operative to accomplish the desired function. Air flow may be passive, or dynamic and accomplished by an exemplary fan or blower apparatus.

[0069] FIG. **4** refers to the evaporation of water and other volatiles while a screen **52** is placed over the drying bin **48**.

[0070] An exemplary drying bin **48** has netting or a screen **52** draped across the drying bin **48** to allow moisture to escape. In an alternative embodiment, the drying in **48** has a fitted lid operative to allow appropriate airflow through. In one embodiment, drying may occur in a drying room with an appropriate humidity and moisture level sensor. The drying room may be kept at a constant temperature and at a positive pressure to avoid bugs or other vermin, and as such the drying may occur without the use of a screen **52** or netting. In a further alternative embodiment, the chew may be transferred into an oven in order to drive off excess moisture and volatile compounds. This drying step dries off approximately 6-13% of the total weight of the chew.

[0071] FIG. **5**A refers to placing the chew **54** into a package that can be either a pouch **56** or a puck-like container **58**.

[0072] Once the moisture level reaches a desired state, the bins that have been dried are then put into the packaging process. In some embodiments, the product **54** provided herein can be placed into a container, such as a puck-like container **58** (can), a bag, or a pouch **56**. These containers may be packaged by hand or machinery operative to do so. The containers have a known tare weight, and the desired package is packed with chew **54** product. It is then weighed, either by an individual, or by the packing machine to determine its weight. If the weight is within range of the desired packing weight (dependent on moisture content), then it is ready to continue on the process of making it. If the weight is too high, then the chew **54** may be returned to an exemplary drying bin **48** to allow additional moisture and volatiles to escape.

[0073] In some embodiments, the compositions provided herein can be used to form a sort of loose leaf smokeless product, or a smokeless product in a finely ground or cut or shredded, a moist cut form, a milled form, a powder form, a pouch form, or snus. In some embodiments, the products provided herein can be used to form a smokeless chew product that includes a dipping product, a dip product, or a snus product. All of these are referred to as "the chew" or "chew" or "chew product" herein. As such, the product is not to be ingested, but stuck under the lip and 'dipped' like traditional chewing tobacco.

[0074] An alternative embodiment provides for a pouch made out of filter paper. The exemplary pouch is operative to allow the chew composition to mix with a user's saliva or other source of moisture and allow a free exchange of flavor, sweeteners, and other components within the chew, but otherwise retain the composition to prevent the chew from dispersing itself through a user's mouth. In an exemplary embodiment, the filter paper is a coffee filter like material, however it will be understood that the filter may be any material with appropriate sized apertures to effectuate the proper exchange of flavors, sweeteners and other components with a mouth of a user.

[0075] When manufacturing the pouches containing the chew composition, the process or method of manufacture may differ slightly. Namely, when manufacturing pouches filled with the composition, all of the dry ingredients are mixed in a mixer, and then put into the pouch using a pouch forming machines. The wet ingredients are mixed separately in a different mixer, using the whisk attachment, and then poured on pre-weighed bins of dry pouches. In one exemplary method of manufacture, all pouch products have the same dry ingredients, so this allows the method of manufacture to produce the dry pouches in bulk and then store them in large bins. When a certain flavor needs to be made, the method permits for the weighing out the amount of pouches needed for one batch, and then pour the liquid mixture (i.e., flavor, plus other wet ingredients, such as liquid synthetic nicotine, amongst others) on the pouches. The pouches containing the dry materials then absorb the wet ingredients.

[0076] FIG. **5**B refers to sealing the containers with a seam in a pouch **60** or in a can **62** with lid **64**. Once the packages are packed, the labels are applied and the packaged chew is stored. Sometimes the packaged chew may be stored in a warehouse at ambient temperature. Storage at ambient temperature is usually sufficient when a large volume of packaged chew is manufactured and sold at a relative quick pace. In other instances, the packaged chew may be stored in a cooler, however it is not required. Cooler temperatures may be thought to help with the labels to prevent bleeding of the chew out of the package. Condensation can form when warm air holding water in a vapor, cools down and that cooler air can no longer hold the same amount of moisture. This moisture collects on a cold surface in very tiny droplets almost a mist and those tiny droplets will congregate to form even bigger droplets that can then start running down the walls of the container quickly get absorbed into the nearest water absorbing material, which is usually the paper of the label itself. Therefore, at times, if the chew is in a can and paper labels are put on and the product is left on a shelf, some of the liquid may bleed out because the can lids do not create a perfect seal to avoid this moisture. However, when the packages are cooled or kept in a refrigerated state, the bleeding through the label is lessened or reduced. This is likely because the condensation is reduced as the cold air does not hold as much water as the warm air left within the packaging. As such, unsightly packaging as well as rejected packaging is reduced. Again, the refrigerated storage is a possibility, but not required.

[0077] In some embodiments, the chew can be packaged, and/or treated in a nitrogen or other inert gas environment or with nitrogen gas or other inert gas to reduce the amount of oxidation of particular components (e.g., flavors and/or nicotine) in the final product. This can help to extend the product stability over an extended shelf life.

[0078] FIG. **6** relates to a method for manufacturing the chew **600**. The method **600** comprising the steps of: measuring ingredients, including non-tobacco ingredients including plant material and a starch, a sweetener, natural and artificial flavors, a pH adjuster, water, salt, and optionally nicotine **602**, adding said ingredients into a mixer **604**, mixing said ingredients in the mixer **606**, drying the mixed ingredients **608**, and packaging the ingredients into a package **610**.

[0079] FIG. **7** relates to an alternative embodiment of a method for manufacturing the chew **700**. In some embodiments, prior to measuring the ingredients **702**, it may be determined that the starch may need to be a proper color **702** i.e. dyed, in order to better mimic tobacco containing products. If this determination is that the color is not proper, the starch is dyed **704**. For example, in an embodiment using arrowroot, before the arrowroot is mixed it with the rest of the ingredients, 1.75 oz of brown liqua-gel food coloring per pound of arrowroot is added to a mixer, it is mixed on low

for 30 minutes. Then, it is placed in bins to dry for a minimum of 12 hours. If it is then the proper color, it is then measured out with the rest of the ingredients **602** and added to a mixer **604**. Of course, this is but one embodiment and depending on the color of the resultant starch or modified starch this may or may not need to be done. Alternative embodiments may use different concentrations of dye and different colors to effectuate desired color of the end product.

[0080] In an alternative embodiment, after mixing of the ingredients **606**, it is then determined if the ingredients are sufficiently mixed **706**. If they are not, the ingredients are returned to the mixer **604** and mixed again **606**. If they are sufficiently mixed, the now mixed ingredients are dried **608**.

[0081] After drying **608**, the mixed ingredients are tested to determine their moisture content **708**. If the test is not within desired range, the mixed ingredients are returned to drying **608**. If the moisture content of the mixed ingredients is within proper range, they are placed into packaging **610**. In an exemplary embodiment, if it is not dry enough, the chew material is returned to be further dried. In an alternative embodiment, if it is too dry, it may be rewetted with additional solvent and returned to adequately dry a subsequent time.

[0082] As they are passed to packaging **610**, they are weighed to determine the amount of product within the package **710**. If the package is too heavy, it is returned to the start of the packaging step. If the package is within proper weight it is passed along to sealing **712**.

[0083] After the package is sealed **712**, it is placed in a storage area **714**, the purpose of which is described above. After the package has been in the stored area for a requisite time, the package is checked for leaks **716**, which may occur during the time upon which five packaged cans are put into the plastic sleeve. If the package shows any leak, seepage or otherwise failure, the package is discarded **718**. If the package is substantially free of any leaks or seepage, it is able to be sold **720**.

EXAMPLES

[0084] Exemplary embodiments of a chew product **54** utilizing principals described herein are further illustrated by the following examples which are set forth to illustrate the presently disclosed subject matter and are not to be construed as limiting. All percentages are a weight percentage of the total mixture.

Example 1—"Classic" Flavored Full Nicotine Chew Using Liquid Synthetic Nicotine

[0085] Approximately 27-31% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 15%-23% sweetener in the form of molasses **34** and xylitol **28**, about 20% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 20-24% water **36** added, about 0.7% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.5% liquid synthetic nicotine **40** is added to a mixer and mixed.

[0086] In Example 1, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 2 below).

[0087] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 2—"Classic" Flavored Full Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0088] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 23% sweetener in the form of molasses **34** and xylitol **28**, about 21% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 0.7% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.35% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0089] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 3—"Classic" Flavored Half Nicotine Chew Using Liquid Synthetic Nicotine

[0090] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 23% sweetener in the form of molasses **34** and xylitol **28**, about 21% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 2.1% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.25%-0.3% nicotine **40** is added to a mixer and mixed.

[0091] In Example 3, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 4 below).

[0092] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 4—"Classic" Flavored Half Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0093] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 23% sweetener in the form of molasses **34** and xylitol **28**, about 21% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 2.1% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 1.7% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0094] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 5—"Classic" Flavored Nicotine-Free Chew

[0095] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34** and xylitol **28**, about 22% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 5.4% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and no nicotine is added, and the ingredients are mixed.

[0096] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 6—Mint Flavored Full Nicotine Chew Using Liquid Synthetic Nicotine

[0097] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34** and xylitol **28**, about 25% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 20% water **36** added, about 0.7% salt, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.425%-0.5% nicotine **40** is added to a mixer and mixed.

[0098] In Example 6, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 7 below).

[0099] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 7—Mint Flavored Full Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0100] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34** and xylitol **28**, about 25% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 20% water **36** added, about 0.7% salt, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.33% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0101] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 8—Mint Flavored Half Nicotine Chew Using Liquid Synthetic Nicotine

[0102] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34**, about 25% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.25%-0.3% nicotine **40** is added to a mixer and mixed.

[0103] In Example 8, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 9 below).

[0104] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 9—Mint Flavored Half Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0105] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34**, about 25% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about

1.7% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0106] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 10—Mint Flavored Nicotine-Free Chew

[0107] Approximately 28% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34**, about 25% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 3% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, and 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and no nicotine is added, and the ingredients are mixed.

[0108] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 11—Wintergreen Flavored Full Nicotine Chew Using Liquid Synthetic Nicotine

[0109] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 19% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **34** added, about 0.1% plasticizer **42** in the form of propylene glycol, about 0.7% **26** salt, 0.9% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.4%-0.5% nicotine **40** is added to a mixer and mixed.

[0110] In Example 11, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 12 below).

[0111] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 12—Wintergreen Flavored Full Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0112] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 19% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **34** added, about 0.1% plasticizer **42** in the form of propylene glycol, about 0.7% **26** salt, 0.9% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.3%-0.4% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0113] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 13—Wintergreen Flavored Half Nicotine Chew Using Liquid Synthetic Nicotine

[0114] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 19% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 1.8% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.9% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.25-0.35% nicotine **40** is added to a mixer and mixed.

[0115] In Example 13, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 14 below).

[0116] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 14—Wintergreen Flavored Half Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0117] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 19% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 1.8% plasticizer **42** in the form of propylene glycol, about 0.7% salt **26**, 0.9% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.17% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added to a mixer and mixed.

[0118] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 15—Wintergreen Flavored Nicotine-Free Chew

[0119] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 19% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 3.6% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.9% pH adjusters, including ammonium salt **22** and baking soda **24**, and no nicotine is added, and the ingredients are mixed.

[0120] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 16—Cherry Flavored Full Nicotine Chew Using Liquid Synthetic Nicotine

[0121] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 23% sweetener in the form of molasses **34** and xylitol **28**, about 17% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 5% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.45%-0.5% nicotine **40** is added.

[0122] In Example 16, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 17 below).

[0123] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 17—Cherry Flavored Full Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0124] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 23% sweetener in the form of molasses **34** and xylitol **28**, about 17% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 22% water **36** added, about 5% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.35% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added.

[0125] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 18—Cherry Flavored Half Nicotine Chew Using Liquid Synthetic Nicotine

[0126] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 25% sweetener in the form of molasses **34** and xylitol **28**, about 18% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 4% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.25%-0.3% nicotine **40** // is added.

[0127] In Example 18, since liquid synthetic nicotine is used, the volume of liquid synthetic nicotine is greater than some of the other examples that utilize tobacco-derived nicotine inasmuch as the presence of both R nicotine isomers and S nicotine isomers. Thus, the overall liquid synthetic nicotine volume must be increased to increase the amount of S nicotine isomers in the composition that provide the desired physiological effects to the user as compared to volume of liquid nicotine that would be used if the liquid nicotine was tobacco-derived (See Example 19 below).

[0128] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 19—Cherry Flavored Half Nicotine Chew Using Liquid Nicotine (Either Tobacco-Derived or Synthetic

[0129] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 25% sweetener in the form of molasses **34** and xylitol **28**, about 18% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 4% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and about 0.17% nicotine **40**, which may be liquid synthetic nicotine or liquid tobacco-derived nicotine, is added.

[0130] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 20—Cherry Flavored Nicotine-Free Chew

[0131] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 25% sweetener in the form of molasses **34** and xylitol **28**, about 18% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 6% plasticizer **42**, in the form of propylene glycol, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and no nicotine is added, and the ingredients are mixed.

[0132] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 21—Peach Flavored Full Nicotine Chew

[0133] Approximately 27% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 21% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water added, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and 3.2%-5% liquid synthetic nicotine **40** is added and the ingredients are mixed in a mixer.

[0134] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 22—Berry Flavored Full Nicotine Chew

[0135] Approximately 27% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **34** are added, along with about 21% sweetener in the form of molasses **34**, about 26% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 21% water **36** added, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and 0.32%-0.5% liquid synthetic nicotine **40** is added.

[0136] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

Example 23—Bourbon Flavored Full Nicotine Chew

[0137] Approximately 29% of tobacco alternative plant materials including spearmint leaves **30** and dyed arrowroot powder **32** are added, along with about 22% sweetener in the form of molasses **34**, about 21% flavorants in the form of various liquid and powder forms **18**, **20**, **38**, about 24% water **36** added, about 0.7% salt **26**, 0.7% pH adjusters, including ammonium salt **22** and baking soda **24**, and 0.34%-0.5% liquid synthetic nicotine **40** is added, and the ingredients are mixed.

[0138] This example, as well as all of the remaining examples may be mixed, dried, and subsequently processed and packaged in any way consistent with the disclosure herein, preferably in a pouch but may also be free form. The resultant chew has a texture and color substantially similar to tobacco containing chews.

[0139] Also, various inventive concepts may be embodied as one or more methods, of which an example has been provided. The acts performed as part of the method may be ordered in any suitable way. Accordingly, embodiments may be constructed in which acts are performed in an order different than illustrated, which may include performing some acts simultaneously, even though shown as sequential acts in illustrative embodiments.

[0140] While various inventive embodiments have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and/or structures for performing the function and/or obtaining the results and/or one or more of the advantages described herein, and each of such variations and/or modifications is deemed to be within the scope of the inventive embodiments described herein. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the inventive teachings is/are used. Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific inventive embodiments described herein. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claims and equivalents thereto, inventive embodiments may be practiced otherwise than as specifically described and claimed. Inventive embodiments of the present disclosure are directed to each individual feature, system, article, material, kit, and/or method described herein. In addition, any combination of two or more such features, systems, articles, materials, kits, and/or methods, if such features, systems, articles, materials, kits, and/or methods are not mutually inconsistent, is included within the inventive scope of the present disclosure.

[0141] All definitions, as defined and used herein, should be understood to control over dictionary definitions, definitions in documents incorporated by reference, and/or ordinary meanings of the defined terms.

[0142] At least a portion of the nicotine product present in the nicotine replacement composition is synthetic. As used herein, the term "synthetic" means that the identified compound (e.g., nicotine) is prepared through a chemical process that does not include deriving/extracting the nicotine from a naturally occurring source, such as tobacco leaves. The terms "tobacco derived," "natural" and "non-synthetic" may used interchangeably herein, and refer to the identified compound or composition that is derived from or extracted from a natural source (such as, for example, tobacco). For example, as used herein, "tobacco derived nicotine," "natural nicotine" and "non-synthetic nicotine" refer to nicotine derived from or extracted from tobacco leaves, and does not encompass nicotine produced from independent chemical synthesis.

[0143] The articles "a" and "an," as used herein in the specification and in the claims, unless clearly indicated to the contrary, should be understood to mean "at least one." The phrase "and/or," as used herein in the specification and in the claims (if at all), should be understood to mean "either or both" of the elements so conjoined, i.e., elements that are conjunctively present in some cases and disjunctively present in other cases. Multiple elements listed with "and/or" should be construed in the same fashion, i.e., "one or more" of the elements so conjoined. Other elements may optionally be present other than the elements specifically identified by the "and/or" clause, whether related or unrelated to those elements specifically identified. Thus, as a non-limiting example, a reference to "A and/or B", when used in con-

junction with open-ended language such as "comprising" can refer, in one embodiment, to A only (optionally including elements other than B); in another embodiment, to B only (optionally including elements other than A); in yet another embodiment, to both A and B (optionally including other elements); etc. As used herein in the specification and in the claims, "or" should be understood to have the same meaning as "and/or" as defined above. For example, when separating items in a list, "or" or "and/or" shall be interpreted as being inclusive, i.e., the inclusion of at least one, but also including more than one, of a number or list of elements, and, optionally, additional unlisted items. Only terms clearly indicated to the contrary, such as "only one of" or "exactly one of," or, when used in the claims, "consisting of," will refer to the inclusion of exactly one element of a number or list of elements. In general, the term "or" as used herein shall only be interpreted as indicating exclusive alternatives (i.e. "one or the other but not both") when preceded by terms of exclusivity, such as "either," "one of," "only one of," or "exactly one of." "Consisting essentially of," when used in the claims, shall have its ordinary meaning as used in the field of patent law.

[0144] As used herein in the specification and in the claims, the phrase "at least one," in reference to a list of one or more elements, should be understood to mean at least one element selected from any one or more of the elements in the list of elements, but not necessarily including at least one of each and every element specifically listed within the list of elements and not excluding any combinations of elements in the list of elements. This definition also allows that elements may optionally be present other than the elements specifically identified within the list of elements to which the phrase "at least one" refers, whether related or unrelated to those elements specifically identified. Thus, as a non-limiting example, "at least one of A and B" (or, equivalently, "at least one of A or B," or, equivalently "at least one of A and/or B") can refer, in one embodiment, to at least one, optionally including more than one, A, with no B present (and optionally including elements other than B); in another embodiment, to at least one, optionally including more than one, B, with no A present (and optionally including elements other than A); in yet another embodiment, to at least one, optionally including more than one, A, and at least one, optionally including more than one, B (and optionally including other elements); etc.

[0145] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0146] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal", "lateral" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0147] Although the terms "first" and "second" may be used herein to describe various features/elements, these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed herein could be termed a second feature/element, and similarly, a second feature/element discussed herein could be termed a first feature/element without departing from the teachings of the present invention.

[0148] An embodiment is an implementation or example of the present disclosure. Reference in the specification to "an embodiment," "one embodiment," "some embodiments," "one particular embodiment," or "other embodiments," or the like, means that a particular feature, structure, or characteristic described in connection with the embodiments is included in at least some embodiments, but not necessarily all embodiments, of the invention. The various appearances "an embodiment," "one embodiment," "some embodiments," "one particular embodiment," or "other embodiments," or the like, are not necessarily all referring to the same embodiments.

[0149] If this specification states a component, feature, structure, or characteristic "may", "might", or "could" be included, that particular component, feature, structure, or characteristic is not required to be included. If the specification or claim refers to "a" or "an" element, that does not mean there is only one of the element. If the specification or claims refer to "an additional" element, that does not preclude there being more than one of the additional element.

[0150] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/−0.1% of the stated value (or range of values), +/−1% of the stated value (or range of values), +/−2% of the stated value (or range of values), +/−5% of the stated value (or range of values), +/−10% of the stated value (or range of

values), etc. Any numerical range recited herein is intended to include all sub-ranges subsumed therein.

[0151] Additionally, any method of performing the present disclosure may occur in a sequence different than those described herein. Accordingly, no sequence of the method should be read as a limitation unless explicitly stated. It is recognizable that performing some of the steps of the method in a different order could achieve a similar result.

[0152] In the claims, as well as in the specification above, all transitional phrases such as "comprising," "including," "carrying," "having," "containing," "involving," "holding," "composed of," and the like are to be understood to be open-ended, i.e., to mean including but not limited to. Only the transitional phrases "consisting of" and "consisting essentially of" shall be closed or semi-closed transitional phrases, respectively, as set forth in the United States Patent Office Manual of Patent Examining Procedures.

[0153] In the foregoing description, certain terms have been used for brevity, clearness, and understanding. No unnecessary limitations are to be implied therefrom beyond the requirement of the prior art because such terms are used for descriptive purposes and are intended to be broadly construed.

[0154] Moreover, the description and illustration of various embodiments of the disclosure are examples and the disclosure is not limited to the exact details shown or described.

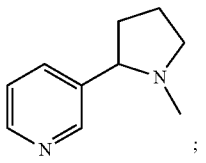
What is claimed is:

1. A composition comprising:

a non-tobacco leaf material comprising a combination of spearmint leaves and arrowroot;

a flavorant, wherein the flavorant comprises capsaicin adapted to produce a burning sensation upon contact with a tissue during chewing usage;

liquid synthetic nicotine that is not derived from tobacco, wherein the liquid synthetic nicotine is (R,S)-nicotine that comprises S nicotine isomers and R nicotine isomers and has the following structure:



;

a ratio of S nicotine isomers to R nicotine isomers in the liquid synthetic nicotine in a range from about 3:1 to about 1:3;

the liquid synthetic nicotine having a weight that is in a range from about 0.15% to about 0.5% of the total weight of the composition;

a diluent, wherein the diluent is operative to dilute the synthetic nicotine to a lower concentration, while maintaining the weight that is in the range from 0.3% to 0.5% of a total weight of the composition, and wherein a ratio of diluent to liquid synthetic nicotine is about 3:1, wherein an amount of free nicotine in the liquid synthetic nicotine, after being exposed to the diluent and an alkaline pH equals an amount of free nicotine in the liquid synthetic nicotine in an undiluted concentration at a neutral or acidic pH;

a pH adjuster comprising at least one of baking soda and an ammonium salt, wherein the pH adjuster maintains the composition at a pH greater than 8.0; and

wherein the composition is adapted to be packaged in a pouch or a can and the composition adapted to deliver the liquid synthetic nicotine during chewing usage.

2. A composition comprising:

a non-tobacco leaf material;

a flavorant; and

liquid synthetic nicotine that is not derived from tobacco, wherein the liquid synthetic nicotine comprises S nicotine isomers and R nicotine isomers;

a ratio of S nicotine isomers to R nicotine isomers in the liquid synthetic nicotine in a range from about 3:1 to about 1:3; and

the liquid synthetic nicotine having a weight that is in a range from about 0.15% to about 0.5% of the total weight of the composition;

wherein the composition is adapted to be packaged in a pouch or a can and the composition adapted to deliver the liquid synthetic nicotine during chewing usage.

3. The composition of claim **2**, wherein the ratio of S nicotine isomers to R nicotine isomers in the liquid synthetic nicotine that is not derived from tobacco is in a range from about 2:1 to about 1:2.

4. The composition of claim **3**, wherein the flavorant comprises capsaicin adapted to produce a burning sensation upon contact with a tissue during chewing usage.

5. The composition of claim **2**, wherein the ratio of S nicotine isomers to R nicotine isomers in the liquid synthetic nicotine that is not derived from tobacco is about 1:1.

6. The composition of claim **2**, further comprising a diluent, wherein the diluent is operative to dilute the synthetic nicotine to a lower concentration, while maintaining the weight that is in the range from 0.3% to 0.5% of a total weight of the composition.

7. The composition of claim **6**, further comprising a ratio of diluent to liquid synthetic nicotine in a range from about 2:1 to about 4:1.

8. The composition of claim **7**, wherein the ratio of diluent to liquid synthetic nicotine is about 3:1.

9. The composition of claim **7**, wherein an amount of free nicotine in the liquid synthetic nicotine, after being exposed to the diluent and an alkaline pH approximates a similar amount of free nicotine in an undiluted concentration at a neutral or acidic pH.

10. The composition of claim **7**, further comprising a pH adjuster.

11. The composition of claim **10**, wherein the pH adjuster includes at least one of baking soda and an ammonium salt.

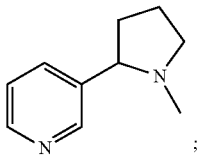
12. The composition of claim **11**, wherein pH adjuster maintains the composition at a pH of about 8.6.

13. The composition of claim **10**, wherein the non-tobacco leaf material comprises shredded spearmint leaves and arrowroot.

14. The composition of claim **6**, wherein the composition has a pH greater than 8.

15. The composition of claim **14**, wherein the composition has a pH of about 8.6.

16. The composition of claim **2**, wherein the liquid synthetic nicotine has the following structure:



;

and the liquid synthetic nicotine is a product of a process comprising:

reacting a nicotinate ester with N-vinyl-2-pyrrolidinone in the presence of a base and a solvent to form a first mixture;

combining the first mixture with a cold acid solution to form a second mixture comprising an aqueous layer;

separating the aqueous layer from the second mixture;

combining the separated aqueous layer with an acid to form a third mixture;

combining the third mixture with a base to form a fourth mixture comprising myosamine; and

reducing the myosamine to nornicotine using a reducing agent; and

methylating the nornicotine to yield (R,S)-nicotine.

* * * * *