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(54) A SMOKELESS ARTICLE

(57) A smokeless article for oral consumption including a pouch containing a first particle population comprising a plurality of particles; in the first particle population the particles comprise a core comprising a nicotinic compound, wherein the core is encapsulated by a continuous coating of a non-porous, saliva-stable material, and wherein the coating is frangible, such that in use the coating fractures on chewing.

Also described are embodiments wherein the pouch further comprises a second particle population comprising a plurality of particles; in the second population the particles comprise a core comprising a nicotinic compound, wherein the nicotinic compound is releasable on exposure of the second particle population to saliva. Also described is a method of manufacturing a smokeless articles for oral consumption the method including forming a first population of particles by applying a coating material to encapsulate each of a plurality of cores each core comprising a nicotinic compound, the coating being a continuous coating of a non-porous, saliva-stable material; wherein the coating is frangible; forming a porous pouch containing the first population of particles; optionally forming a second population of particles each core comprising a nicotinic compound which is releasable on exposure of the second particle population to saliva and incorporating the second population of particles into the porous pouch in a predetermined ratio with the first population of particles; and a step of sealing the pouch.

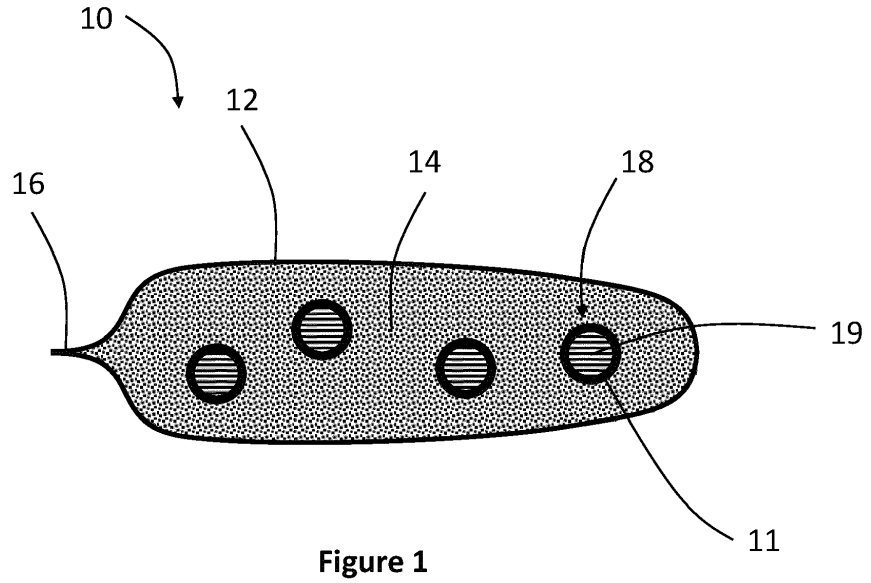

Figure 1

EP 3 837 995 A1

Description

Field of the Invention

[0001] The present invention relates to a smokeless article for oral consumption, and a method of manufacturing a smokeless article for oral consumption.

Background

[0002] Smoking is generally considered to expose a smoker to potentially harmful substances. It is generally thought that the majority of the potentially harmful substances are formed by the heat generated during burning (combustion) of the article. There is interest in so-called heat not burn products, which heat a tobacco or similar substrate at a lower temperature than a conventional cigarette. These products are usually described as less harmful than conventional cigarettes. Both conventional cigarettes and heat not burn products are visible during use and produce smoke or vapour.

[0003] As a result of these considerations and because of consumer preferences, it is desirable to find and improve alternative substance delivery routes that continue to meet user expectations. Smokeless articles are a suitable alternative because they do not require heating for substance delivery to the user. Instead, smokeless articles rely on saliva to extract soluble substances, typically nicotine and/or flavours, from tobacco contained within the smokeless article.

[0004] Conventional smokeless articles have a saliva permeable pouch housing a content. The content is generally in the form of tobacco. Said tobacco containing a soluble element, typically nicotine. Such a product may be referred to as portion snus. It is typically provided as prepackaged (traditionally moist) powder in small teabag-like pouches. Each pouch is a single portion or unit. This moistened product may be referred to as original snus.

[0005] Smokeless articles are placed in the mouth where saliva extracts the soluble element from the tobacco contained within. Typically, the smokeless article is placed in the oral cavity, sublingually or in the oral vestibule (between the teeth and lips/cheeks). The user may assist extraction by oral manipulation, such as by chewing and/or sucking or pressing on the outside of the mouth to squeeze the pouch.

[0006] The resulting saliva, which contains extracts, subsequently contacts a mucous membrane in the mouth, or at another point of the gastrointestinal tract, to deliver the soluble element across the membrane and into the bloodstream. The soluble element is then transported by the bloodstream to the site of action. For example, nicotine is delivered to the brain where it acts upon acetylcholine receptors.

[0007] The above described extraction and delivery process continues until the soluble element is depleted from the smokeless article. The smokeless article must then be removed from the mouth and disposed of.

[0008] Some commercially available smokeless articles contain snuff. Snuff is smokeless tobacco made from ground or pulverised tobacco leaves. Snuff is available in dry form or wet (moist) form. Moist snuff may be referred to as snus. Two common varieties of snus are Scandinavian snus and American snus. Both varieties of snus are available in a loose form, but are often contained within a saliva permeable pouch.

[0009] Typically, production of snus is achieved by grinding a blend of leaf tobaccos to specified particle sizes. The ground tobacco is then mixed with water and sodium chloride in closed process blenders. The mixture is subjected to a heat treatment, involving temperatures up to 80 - 100 °C, for several hours to pasteurize the snus. Thereafter, the snus is cooled and other ingredients may be added. Snus is typically manufactured to meet the GothiaTek® standard, as detailed in "Swedish snus and the GothiaTek® standard" (2005), Rutqvist, et al.

[0010] The World Health Organisation states that smokeless articles are considerably less hazardous than cigarettes. Action on Smoking and Health considers smokeless articles to be about one hundred times less harmful than cigarettes. Smokeless articles are therefore thought to provide a healthier alternative for smokers.

[0011] Typical snus products release nicotine in a continuous manner following contact of the nicotine-containing material with saliva in the oral cavity with the concentrations of nicotine in the user's mouth decreasing overtime as the nicotine in the snus product is depleted.

[0012] There is a need for improved design of smokeless articles to enhance the user experience and improve the function of its constituent components.

[0013] The present disclosure has been devised in the light of the above considerations.

Summary of the Invention

[0014] As used herein, the term "content(s)" is intended to refer to compounds, material and/or substances that may be enclosed within the pouch.

[0015] As used herein, the term "nicotinic compound" is intended to refer to nicotine, nicotine salt(s), nicotine complex(es); and/or nicotine solvate(s).

[0016] As used herein, the term "non-porous" is intended to refer to a material that does not include any pores extending through the thickness of the wall (for instance, "through holes" or capillaries).

[0017] As used herein, the term "saliva-stable" is intended to refer to a material that does not substantially dissolve or disintegrate as a result of exposure to saliva in the oral cavity of the user at physiological temperature. Therefore a layer of such material is resistant to the migration of saliva (or compounds/substances dissolvable in saliva, for example nicotinic compounds) through the thickness of the material. The material may also be resistant to migration of saliva (or compounds/substances dissolvable in saliva e.g. nicotinic compounds) by phase

transfer mechanisms. In some cases a standard commercially available artificial saliva may be used to test saliva-stability.

[0018] Alternatively, "saliva-stable" may equate to "water-stable" and refer to a material that does not substantially dissolve or disintegrate as a result of exposure to water in the oral cavity of the user at physiological pH. In such cases, a layer of the material is resistant to the migration of water (or compounds/substances dissolvable in water, for example nicotinic compounds) through the thickness of the material. The material may also be resistant to migration of water (or compounds/substances dissolvable in water e.g. nicotinic compounds) by phase transfer mechanisms.

[0019] As used herein, the term "saliva" is intended to refer to the liquid substance formed in the mouth of animals, such as humans, that includes water, electrolytes and enzymes. Other components of saliva may include mucus, white blood cells, epithelial cells and/or antimicrobial agents.

[0020] As used herein, the term "hydrophobic" is intended to refer to a material having water contact angle greater than 90°, such that the material is resistant to adsorption and/or absorption of water. In some instances such material may have a polarity lower than that of water.

[0021] As used herein, the term "plant material" is intended to refer to a portion and/or part(s) of a plant (e.g. leaf, stem, flower or bud). The plant material may be processed (for example, by shredding, grinding or drying) or it may be non-processed (that is, used whole). The plant material is typically fibrous (comprising or characterised by fibres). For the avoidance of doubt, the term "plant material" is not intended to include pulp and/or paper which is derived from a plant material (typically wood) and chemically and/or mechanically processed to extract fibres before use.

[0022] As used herein, the term "moisture content" may include water, humectants, liquid flavourants and/or other liquid compounds.

[0023] As used herein, the term "oral consumption" is intended to refer to any oral administration route achieved by placing the smokeless article into the oral cavity. This includes, but is not limited to, buccal, sublingual, periodontal, gingival and ingestion.

[0024] According to a first aspect there is provided a smokeless article for oral consumption comprising a pouch containing a first particle population comprising a plurality of particles; in the first particle population the particles comprise a core comprising a nicotinic compound, wherein the core is encapsulated by a continuous coating of a non-porous, saliva-stable material, and wherein the coating is frangible, such that in use the coating fractures on chewing..

[0025] In this the way, when the smokeless article is inserted into the user's mouth the coating of a non-porous, saliva-stable material prevents saliva (or water) from contacting the core of the coated first population of particles in the pouch. The non-porous, saliva-stable material also acts to prohibit migration of the nicotinic compound from the core into the user's oral cavity. Therefore, release of the nicotinic compound from the first population of particles within the pouch into the user's oral cavity is prevented.

[0026] In some cases the pouch further comprises a second particle population comprising a plurality of particles; in the second population the particles comprise a core comprising a nicotinic compound, wherein the nicotinic compound is releasable on exposure of the second particle population to saliva.

[0027] In contrast to the first population of particles, due to the lack of non-porous, saliva-stable coating, the release of the nicotinic compound from the second population of particles starts immediately on exposure of the second population to saliva in the user's mouth.

[0028] The frangible nature of the coating on the first population of particles enables the user to bite down or chew on the particles in the pouch to break the coating. This exposes a portion of the particulate core that was previously covered by the coating, and facilitates access of saliva (or water) from the user's oral cavity to the nicotinic compound in the core. Subsequently, the saliva extracts soluble components (in particular, the nicotinic compound) contained within the core of the first population of particles, and delivers the extracted components from the particles into the user's oral cavity. This provides a level of user control over the timing of release of the nicotinic compound after insertion of the pouch into the mouth. Insertion of the pouch into the mouth may result in an initial release of nicotinic compound as saliva penetrates any second population of particles that is present or any other source of nicotinic compound in the pouch, followed by at least one further release of nicotinic compound from the first population of particles that is initiated by chewing. The user has complete control over when the release of the nicotinic compound from the first population of particles is initiated. For instance, when a "hit" of nicotinic compound is desired by the user, they can simply bite down on the pouch to break the frangible coating on the first population of particles and initiate release of the nicotinic compound. The provision of the coating on the plurality of particles in the first population also allows the user to obtain multiple "hits" of nicotinic compound from a single pouch. In preferred cases a single bite on the pouch will not fracture the coating on all of the particles of the first population in the pouch. Preferably a first bite on the pouch will fracture the frangible coating only on a subset of the particles with subsequent bites fracturing the coating on further subsets of the particles to provide further "hits" of nicotinic compound, thus providing the user with the ongoing ability to repeat the "hit" multiple times from a single pouch.

[0029] Preferably all of the nicotinic compounds present in the smokeless article are in the cores of the plurality of particles, i.e. the release of any nicotinic compound into the oral cavity of a user would require fracture

of the frangible coating on at least a subset of the plurality of particles. In these preferred cases, no nicotinic compounds are present outside the cores of the particles.

[0030] Furthermore, the presence of the continuous coating of non-porous, saliva-stable material imparts an additional benefit that the loss of moisture from the core of the first population of particles prior to use is retarded. The coating retards or prevents the passage of moisture with the result that the rate of loss of moisture from the core material over time is reduced as compared to a smokeless article having no such coating or in which the coating is breached; providing a smokeless article having a longer shelf-life.

[0031] Provision of the coating on the first population of particles within the pouch shields the coating from premature breakage as it is provided on a surface that is within the enclosed volume of the pouch. Provision of the coating on the outer surface of the first population of particles may also have the benefit of reducing or preventing clumping of the core material which can lead to an uneven sensation when the pouch is in use, for example where the core comprises a plant material.

[0032] Preferably, the non-porous, saliva-stable material comprises a polymer.

[0033] In this way, the physical properties of the non-porous, saliva-stable material can easily be tuned by selection of an appropriate material. This is advantageous from a manufacturing and processability perspective. It is also advantageous from the perspective of use of the article. For example, the degree of frangibility of the coating can be tuned be selection of an appropriate material.

[0034] Preferably, the non-porous, saliva-stable material is selected from sorbitol, maltitol, isomalt, mannitol, starch, gelatin, gum arabic, polyvinyl acetate, carob bean gum, refined paraffin wax, shellac, locust bean gum, petroleum wax, terpene resin, tragacanth, polyethylene, xanthan gum, and combinations thereof.

[0035] In this way, a coating with suitable structural and physical properties can be provided.

[0036] Preferably, the non-porous, saliva-stable material is hydrophobic.

[0037] In this way, the coating more effectively repels saliva (or water) to prevent access of saliva (or water) to the core material of the first population of particles.

[0038] Preferably, the core material is tobacco-free.

[0039] Preferably, the particles are tobacco-free.

[0040] Preferably, the content of the pouch is tobacco-free.

[0041] In this way, the user may experience a similar or enhanced recreational/pharmaceutical effect as compared to conventional tobacco-containing products without experiencing undesirable components inherent to tobacco (e.g. tobacco flavour).

[0042] The coating may be applied to the core material by any suitable means, for example, brushing, spraying, or immersion. It is preferred that the coating is uniform across the surface of the core material.

[0043] Preferably, the coating is applied by spray coating.

[0044] In this way, a more uniform application of the coating is achieved. This provides a more consistent user experience.

[0045] Preferably the pouch contains a first and second particle population as described herein.. Preferably the pouch contains only two particle populations. In some cases more than two, e.g. three, four or five particle populations may be included. Preferably the pouch contains no components other than the particle populations (i.e. the first particle population and any further particle populations that are present, e.g. the second particle population).

[0046] Preferably about 20 wt.%, about 25 wt.%, about 50 wt.%, about 75 wt.%, about 80 wt.%, about 90 wt.%, or 100 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population. In some cases 100 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population.

[0047] When first and second particle populations are both present, preferably about 20 wt.%, about 25 wt.%, about 50 wt.%, about 75 wt.%, about 80 wt.% or about 90 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population.

[0048] This control of the distribution of the nicotinic compound in the pouch allows control of the amount of nicotinic compound that can be released upon simple contact with saliva when both first and second particle populations are present in the pouch, i.e. release starts without delay on insertion of the pouch into the user's mouth, as compared to the amount of nicotinic compound that is released upon breaking of the non-porous, saliva-stable coating on the first population of particles, for example upon chewing by the user. When a second particle population is present in the pouch, to ensure an initial release of nicotinic compound without requiring chewing of the article, less than 100 wt.% of the total amount of the nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population.

[0049] Preferably between more than about 5 wt.%, more than about 10 wt.%, more than about 25 wt.%, more than about 50 wt.%, or more than about 75 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population. For example, preferably between about 5 wt.% and about 90 wt.%, between about 10 wt.% and about 75 wt.%, or between about 25 wt.% and about 75 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle population. In this way, the user experiences an initial period of time during which the release of nicotinic compound exhibits a similar profile to that from a traditional snus product but the user can then refresh the release of nicotinic compound as desired by chewing on the pouch. Preferably the user can refresh

the release of nicotinic compound multiple times by chewing the pouch on multiple different occasions during use.

[0050] When first and second particle populations are both present, preferably at least about 10 wt.%, or at least about 25 wt.%, or at least about 50 wt.% of total amount of nicotinic compound in the smokeless article is present in the second particle population.

[0051] When first and second particle populations are both present, preferably the weight ratio of the amount of the nicotinic compound in the first and second particle populations is selected from 5:95, 10:90, 20:80, 25:75, 30:70, 40:60, 50:50, 60:40, 70:30, 75:25, 80:20, 90:10, and 95:5.

[0052] Preferably all of the nicotinic compound present in the smokeless article is contained in the cores of the particles, preferably all in the combination of the first and second particle populations.

[0053] According to a second aspect there is provided a method of manufacturing a smokeless article for oral consumption the method comprising:

(i) forming a first population of particles by applying a coating material to encapsulate each of a plurality of cores each core comprising a nicotinic compound, the coating being a continuous coating of a non-porous, saliva-stable material; wherein the coating is frangible;

(ii) forming a porous pouch containing the first population of particles;

(iii) optionally forming a second population of particles each core comprising a nicotinic compound which is releasable on exposure of the second particle population to saliva and incorporating the second population of particles into the porous pouch in a predetermined ratio with the first population of particles; and

(iv) thermally or chemically sealing the pouch to enclose the population(s) of particles.

[0054] In this way, a method of manufacturing a smokeless article having the advantageous properties as listed in the first aspect is provided. Furthermore, applying the coating material to a plurality of cores before insertion into a pouch and/or sealing of the pouch provides a greater degree of flexibility in the manufacturing of the smokeless articles. For instance, it allows other components to be included in the pouch contents alongside the particles; for example biologically/pharmacologically active compounds, pH stabilisers or adjusters, humectants, flavourants, fillers, preservatives, aqueous/non-aqueous solvents and/or binders. In that case, step ii) of the method described herein may comprise forming a porous pouch containing the plurality of particles and one or more additional components, such as those listed above. In addition, where the second population of particles is incorporated, the incorporation of the first and second populations of particles before sealing of the pouch allows a predetermined ratio of the first and second populations of particles to be achieved. This means that the release characteristics and profile of the nicotinic compound can be tailored according to user preferences so providing an enhanced user experience. The predetermined ratio may be as described herein in relation to the first aspect.

[0055] The coating material is typically applied to the cores of the first population of particles in a spreadable or sprayable state, for example as a liquid or paste. After application, the coating material then becomes frangible overtime, for example upon curing or evaporation of solvent. In some cases the coated cores are only incorporated into the pouch after the coating becomes frangible; this may reduce the chances of particles sticking together if the coating is sticky or tacky prior to becoming frangible, e.g. if it is not fully cured or dried. In some cases, the coating may become non-sticky or non-tacky before the coating dries or cures full to become frangible. In such cases, the coated cores do not stick together on contact and so may be incorporated into the pouch after becoming non-sticky or non-tacky but prior to the coating becoming frangible. As such the method may further include a step of curing or allowing solvent to evaporate from the coating material to form a frangible coating. This step may occur between steps (i) and (ii) above; or between steps (ii) and (iii) above; or between steps (iii) and (iv) above; or between steps (ii) and (iv) if step (iii) is excluded; or following step (iv) above. Preferably this step occurs between steps (i) and (ii) above.

[0056] An advantage of applying the frangible coating to the first population of particles is that the pouch material itself provides some protection to the particles. In this way, the frangible coating on the particles in the resultant smokeless article is protected from pre-mature breakage during storage and/or use.

[0057] Preferably, the coating material is applied by spray-coating.

[0058] In this way, a more uniform application of coating material is achieved. It follows that a more consistent user experience is achieved.

[0059] According to a third aspect there is provided a smokeless article for oral consumption produced by a process according to the second aspect.

[0060] According to a fourth aspect there is provided a kit comprising a plurality of smokeless articles according to the first aspect and/or the third aspect and a container.

[0061] According to a fifth aspect there is provided use of the smokeless article according to either the first aspect and/or the third aspect.

[0062] The smokeless article may be described as a snus article.

[0063] The smokeless article preferably has a mass of about 0.1 g to 5.0 g, such as about 0.5 g to about 4.0 g

or about 1.0 g to about 3.0 g.

[0064] The smokeless article preferably has a length of about 30 mm, such as about 28 mm or 26 mm, a width of about 12 mm, such as about 10 mm or 8 mm, and a depth of about 5 mm, such as about 4 mm or 3 mm.

[0065] The pouch is preferably formed from a porous substrate. The porous substrate may be comprised of one or more materials. The porous substrate may be comprised of fiber, paper, cloth and fabric or combinations thereof. The porous substrate may be comprised of one or more polymeric materials. The polymeric material may be selected from one or more of hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVOH), polyvinylpyrrolidone (PVP), polyethylene oxide (PEO) hydroxyethyl cellulose (HEC), polyethylene glycol (PEG), pullulan, sodium alginate, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, maltodextrin, methylmethacrylate copolymer, carboxyvinyl copolymers, starch and gelatin.

[0066] The porous substrate is typically completely insoluble in saliva. Suitable insoluble porous substrate materials include, but are not limited to, fiber, paper, water-insoluble polymers, cloth and fabric. Suitable soluble porous substrate materials include, but are not limited to, water-soluble polymers such as polyethylene oxide (PEO), hydroxypropyl cellulose (HPC) and hydroxypropyl methylcellulose (HPMC).

[0067] The pouch may be formed by, for example, folding a single sheet of porous substrate on itself or bringing two or more sheets of a porous substrate together and sealing the edges. The edges may initially be partially sealed to provide an open pouch in which the content may be placed before completely sealing the pouch closed. The sheets may be the same thickness or different thicknesses.

[0068] Preferably, at least 50% of the pores of the porous substrate have a diameter of 50 μm to 200 μm, such as 100 μm to 175 μm or 125 μm or 150 μm. At least 50% of the pores have a diameter of at least 100 μm. For example, at least 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95% or 100% of the pores have such diameters.

[0069] The pouch may be coloured or include markings, such as brand logos and text, to improve user perception. The pouch may be partially or completely coloured by a colourant.

[0070] The content may comprise one or more substances either in addition to the particles defined herein, or as incorporated into the cores of some or all of the particles. An advantage of this is that all of the components included in the cores are protected by the coating during storage leading to a longer shelf-life. In some cases the additional substances are not provided in the particle cores. In that case, the smokeless article behaves in a similar way to existing smokeless articles, e.g. in terms of mouthfeel and physical and tactile parameters, leading to higher consumer acceptance. In some cases some additional substances may be incorporated in the cores of the first population of particles (e.g. those requiring more protection during storage) and some may be provided in the cores of any further populations of particles (e.g. the second population of particles) or addition to the particles (e.g. those contributing more to mouthfeel or physical behaviour of the smokeless article).

[0071] The or each substance may individually be a biologically/pharmacologically active compound, pH stabilisers or adjusters, humectants, flavourants, fillers, preservatives, aqueous/non-aqueous solvents and binders. The or each substance may be provided for more than one purpose. In some cases any substances included in addition to the particles defined herein in the pouch are not sources of a nicotinic compound, i.e. the only source of a nicotinic compound in the smokeless article is in the core of the particles.

[0072] The content of the pouch (i.e. the ingredients, material and/or substances enclosed within the pouch) preferably occupies substantially all of the internal volume of the pouch. The content may occupy 80%, 85%, 90%, 95% or 100% of the internal volume of the pouch. The content may comprise a solid material to provide physical integrity, such as an organic material (e.g. plant material) or an inorganic material. Such solid materials may naturally or inherently contain one or more biologically/pharmacologically active compounds and/or additives.

[0073] Preferably the particle population(s) form the entire contents of the pouch, i.e. no additional materials are enclosed in the pouch. Preferably the pouch contains only the first population of particles and no other materials. Preferably the pouch contains only the first and second populations of particles and no other materials.

[0074] The **Nicotinic compound** is selected from nicotine, nicotine salt(s), nicotine complex(es); and/or nicotine solvate(s). Nicotine salts may include a salt selected from the group consisting of nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dehydrate, nicotine sulfate, nicotine zinc chloride monohydrate, nicotine salicylate and mixtures thereof. The nicotinic compound may be provided from a natural or synthetic source. Natural sources include plant materials containing a nicotinic compound, such as Nicotiana species (Tobacco).

[0075] Any type of tobacco may be used. This includes, but is not limited to, flue-cured tobacco, burley tobacco, Maryland Tobacco, dark-air cured tobacco, oriental tobacco, dark-fired tobacco, perique tobacco and rustica tobacco. This also includes blends of the above mentioned tobaccos.

[0076] Any suitable parts of the tobacco plant may be used. This includes leaves, stems, roots, bark, seeds and flowers.

[0077] The tobacco may comprise one or more of leaf tobacco, stem tobacco, tobacco powder, tobacco dust, tobacco derivatives, expanded tobacco, homogenised tobacco, shredded tobacco, extruded tobacco, cut rag

tobacco and/or reconstituted tobacco (e.g. slurry recon or paper recon).

[0078] The content may comprise a gathered sheet of homogenised (e.g. paper/slurry recon) tobacco or gathered shreds/strips formed from such a sheet.

[0079] The sheet may have a grammage greater than or equal to 100 g/m^2, e.g. greater than or equal to 110 g/m^2 such as greater than or equal to 120 g/m^2. The sheet may have a grammage of less than or equal to 300 g/m^2 e.g. less than or equal to 250 g/m^2 or less than or equal to 200 g/m^2. The sheet may have a grammage of between 120 and 190 g/m^2.

[0080] Where the nicotinic compound is provided in tobacco, the cores of the particles may simply comprise, or consist of, tobacco strands. In that situation, the first population of particles comprises tobacco strands coated with the frangible coating as described herein. Any second population of particles (where included) may comprise tobacco strands that are not coated with such a frangible coating (they may have an alternative coating that does not impede release of nicotinic compounds from the tobacco or, preferably, they may be uncoated). This arrangement provides the advantage that the mouthfeel of the smokeless product may be more like a traditional snus due to the second population of particles but the added advantage of the tailored released profile is provided by inclusion of the first population of particles.

[0081] **Biologically/pharmacologically active compounds** are provided to produce a pharmacological effect in the user. Suitable biologically/pharmacologically active compounds include the group consisting of: cocaine, caffeine, opiates and opioids, cathine and cathinone, kavalactones, mysticin, beta-carboline alkaloids, salvinorin A together with any combinations, functional equivalents to, and/or synthetic alternatives of the foregoing. Biologically/pharmacologically active compounds may also have additive properties.

[0082] Preferably the biologically/pharmacologically active compounds included in addition to the nicotinic compound in the coated cores, is a non-nicotinic compound.

[0083] **pH stabilisers or adjusters** may be provided to adjust the user experience and/or modify the bioavailability of a pharmacologically active compound. For instance, under acidic conditions, nicotine is protonated and does not readily cross mucous membranes. Examples of suitable pH stabilisers include ammonia, ammonium carbonate, sodium carbonate and calcium carbonate. The overall pH of the smokeless article is preferably pH 7 to pH 9, such as pH 7.25 to pH 8.75 or pH 7.5 to pH 8.5.

[0084] The overall pH of a smokeless article may be determined by, for example, (i) placing the content of the smokeless article in 10 mL of distilled water (iii) agitating the mixture for at least 5 minutes and (iv) measuring the pH of the solution with a pH probe.

[0085] **Fillers** may be provided to increase the volume of the smokeless article (e.g. by increasing the volume contained within the pouch and to strengthen the content). Suitable fillers include calcium carbonate, calcium phosphate, corn starch, grains, lactose, polysaccharides (e.g. maltodextrin), polyols, sugars (e.g. dextrose, manitol, xylitol, sorbitol), natural fibres (e.g. non-tobacco fibres), microcrystalline cellulose, cellulose and cellulose derivatives (e.g. finely divided cellulose), lignocellulose fibres (e.g. wood fibres), jute fibres and combinations thereof. In some cases, the amount of filler is 5 to 10 wt% of the content e.g. around 6 to 9 wt%.

[0086] **Flavourants** may be provided in solid or liquid form. Suitable flavourants include coffee, eucalyptus, menthol, liquorice, peppermint, spearmint, chocolate, fruit flavour (including e.g. citrus, cherry etc.), vanilla, spice (e.g. ginger, cinnamon) and tobacco flavour. The flavourant may be evenly dispersed throughout the content or may be provided in isolated locations and/or varying concentrations throughout the content. As used herein, the term "flavourant" denotes a compound having a desirable taste, aroma or both.

[0087] **Humectants** may be provided to control moisture content thereby preventing the smokeless article from drying out during storage and reducing the amount of saliva wetting required before the user experience begins. Suitable humectants include polyhydric alcohols (e.g. propylene glycol (PG), triethylene glycol, 1,2-butane diol and vegetable glycerine (VG)) and their esters (e.g. glycerol mono-, di- or tri-acetate).

[0088] The humectant may have a lower limit of at least 1 % by weight of the content such as at least 2 wt%, such as at least 5 wt%, such as at least 10 wt%, such as at least 20 wt%, such as at least 30 wt%, or such as least 40 wt%.

[0089] The humectant may have an upper limit of at most 50% by weight of the contents, such as at most 40 wt%, such as at most 30 wt%, or such as at most 20 wt%, such as at most 10 wt %, such as at most 5 wt %, such as at most 2 wt%.

[0090] Preferably, the amount of humectant is 1 to 40 wt% of the content, such as 2 to 20 wt% or 5 to 10 wt%.

[0091] Smokeless articles having a total moisture content of 10% or less are generally considered to be 'dry'. Smokeless articles having a total moisture content of 40% or more are generally considered to be 'wet'.

[0092] **Sweeteners** may be provided to modify the user taste perception and, in particular, overcome bitter flavours that result from other substances. Suitable sweeteners include honey, sugar, brown sugar, glucose, fructose, sucrose, aspartame, xylitol, maltitol, saccharin sodium, glycyrrhizin tripotassium liquorice, jujube or a mixture thereof. The amount of sweetener is in some cases 1 to 20 % by weight of the content, such as 2 to 15 wt% or 5 to 10 wt%.

[0093] **Stabilisers** are provided to prevent decomposition or degradation over time during storage by, for example, retarding oxidation or unwanted biological activity. Stabilisers may be selected from the group consisting of antioxidants including vitamin E, such as tocopherole,

ascorbic acid, sodium pyrosulfite, butylhydroxytoluene, butylated hydroxyanisole, edetic acid and salts thereof; and preservatives including citric acid, tartaric acid, lactic acid, malic acid, acetic acid, benzoic acid, sorbic acid and salts thereof.

[0094] **Binders** may be provided. Suitable binders include starches and/or cellulosic binders such as methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose and carboxymethyl cellulose, gums such as xanthan, guar, arabic and/or locust bean gum, organic acids and their salts such as alginic acid (sodium alginate), agar and pectins. In some embodiments the amount of binder is 5 to 10 wt% of the content e.g. around 6 to 9 wt% or 7 to 8 wt%.

[0095] **Colourants** may be provided to modify the user impression of the smokeless article. Colourants include whitening agents. Colourants may be selected from one or more of common colourants such as curcumin (E100), turmeric (E100(ii)), riboflavin (E101), riboflavin-5'-phosphate (E101 (ii)), tartrazine (E102), quinoline yellow (E104), riboflavin-5-sodium phosphate (E106), yellow 2G (E107), sunset yellow FCF (E110), carmine, cochineal (E120), azorubine (E122), amaranth (E123), ponceau 4R (E124), erythrosine (E127), red 2G (E128), allura red AC (E129), patent blue V (E131), indigotine (E132), brilliant blue FCF (E133), chlorophylls (E140), copper complexes of chlorophyll (E141), green S (E142), caramel (E150a-d), brilliant black BN (E151), carbon (E153), brown FK (E154), brown HT (E155), alfa-, beta- and gamma- carotene (E160a), annatto, bixin, norbixin (E160b), bell pepper (Paprika) extract (E160c), lycopene (E160d), beta-apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'-carotenic acid (E160f), flavoxanthin (E161a), lutein (E161b), cryptoxanthin (E161c), rubixanthin (E161d), violaxanthin (E161e), rhodoxanthin (E161f), canthaxanthin (E161g), citranaxanthin (E161h), beetroot extract (E162), anthocyanins (E163), calcium carbonate (E170), titanium dioxide (E171), iron oxides (E172), aluminium (E173), silver (E174), gold (E175), lithol rubine BK (E180), tannins (E181). The amount of colourant may be up to about 3% by weight of the smokeless article, such as about 0.5% to about 2.5% or about 1% to about 2%.

[0096] **Plant material** may be provided for physical integrity and may function as a natural source of substances such as, for example, biologically/pharmacologically active compounds, flavourants, pH stabilisers etc. The plant material may comprise least one plant material selected from the list including Amaranthus dubius, Arctostaphylos uva-ursi (Bearberry), Argemone mexicana, Amica, Artemisia vulgaris, Yellow Tees, Galea zacatechichi, Canavalia maritima (Baybean), Cecropia mexicana (Guamura), Cestrum noctumum, Cynoglossum virginianum (wild comfrey), Cytisus scoparius, Damiana, Entada rheedii, Eschscholzia califomica (California Poppy), Fittonia albivenis, Hippobroma longiflora, Humulus japonica (Japanese Hops), Humulus lupulus (Hops), Lactuca virosa (Lettuce Opium), Laggera alata, Leonotis leonurus, Leonurus cardiaca (Motherwort), Leonurus sibiricus (Honeyweed), Lobelia cardinalis, Lobelia inflata (Indian-tobacco), Lobelia siphilitica, Nepeta cataria (Catnip), Nicotiana species (Tobacco), Nymphaea alba (White Lily), Nymphaea caerulea (Blue Lily), Opium poppy, Passiflora incamata (Passionflower), Pedicularis densiflora (Indian Warrior), Pedicularis groenlandica (Elephant's Head), Salvia divinorum, Salvia dorrii (Tobacco Sage), Salvia species (Sage), Scutellaria galericulata, Scutellaria lateriflora, Scutellaria nana, Scutellaria species (Skullcap), Sida acuta (Wireweed), Sida rhombifolia, Silene capensis, Syzygium aromaticum (Clove), Tagetes lucida (Mexican Tarragon), Tarchonanthus camphoratus, Tumera diffusa (Damiana), Verbascum (Mullein), Zamia latifolia (Maconha Brava) together with any combinations, functional equivalents to, and/or synthetic alternatives of the foregoing.

[0097] In some cases any plant material included in addition to the first, and the second (where included), population of particles is not a source of a nicotinic compound; for example it is not a Nicotiana species (Tobacco).

[0098] The content may comprise at least 50 wt% plant material based on the weight of the content, e.g. at least 60 wt% plant material e.g. around 65 wt% plant material. The content may comprise 80 wt% or less plant material e.g. 75 or 70 wt% or less plant material.

[0099] The skilled person will appreciate that except where mutually exclusive, a feature or parameter described in relation to any one of the above aspects may be applied to any other aspect. Furthermore, except where mutually exclusive, any feature or parameter described herein may be applied to any aspect and/or combined with any other feature or parameter described herein.

Summary of the Figures

[0100] Embodiments and experiments illustrating the principles of the invention will now be discussed with reference to the accompanying figures in which:

Figure 1. shows a cross-sectional view of a first embodiment of a smokeless article.

Figure 2. shows a cross-sectional view of a second embodiment of a smokeless article.

Figure 3. shows a cross-sectional view of a third embodiment of a smokeless article.

Figure 4. shows a cross-sectional view of a fourth embodiment of a smokeless article.

Figure 5. shows a nicotine release profile graph for two different embodiments of a smokeless article.

Figure 6. shows a nicotine release profile graph for

two different embodiments of a smokeless article.

Detailed Description of the Invention

[0101] As shown in Figure 1 there is provided a first embodiment of a smokeless article 10 having a pouch 12, the pouch being a porous substrate. The pouch 12 contains a content 14 including particles 18 that are formed of a core 19 having a coating 11 of a non-porous, saliva-stable material surrounding the core. The coating 11 is frangible. The pouch 12 is substantially rectangular. The pouch 12 is formed from a single sheet of a porous substrate and is substantially filled by the content 14. The pouch 12 has a seal 16 along each of the three edges where the inner surface of the single sheet of porous substrate meets itself to seal the contents 14 in the pouch 12.

[0102] In use, the smokeless article 10 is placed into the oral cavity of the user. Due to the coating 11, saliva present in the user's oral cavity is prohibited from contacting the cores 19 of the particles 18 contained within the pouch. Nor can the nicotinic compound in the cores 19 migrate through the coating 11. When the user desires a "hit" of nicotinic compound they bite down or chew on the smokeless article to break the coating 11. This exposes a portion of the core 19, such that saliva can contact the core material. A nicotinic compound within the core 19 is then extracted into the saliva and may enter the user's blood stream by oral consumption to provide a "hit" of nicotinic compound.

[0103] As shown in Figure 2 there is provided a second embodiment of a smokeless article 10 having a pouch 12, the pouch being a porous substrate. The pouch 12 contains a content 14 including a first population of particles 18 that are formed of a core 19 having a coating 11 of a non-porous, saliva-stable material surrounding the core. The coating 11 is frangible. The pouch 12 also contains a second population of particles 13 that are formed of a core 15 but without the coating of non-porous, saliva-stable material. The pouch 12 is substantially rectangular. The pouch 12 is formed from a single sheet of a porous substrate and is substantially filled by the content 14. The pouch 12 has a seal 16 along each of the three edges where the inner surface of the single sheet of porous substrate meets itself to seal the contents 14 in the pouch 12.

[0104] In use, the smokeless article 10 is placed into the oral cavity of the user. Due to the coating 11, saliva present in the user's oral cavity is prohibited from contacting the cores 19 of the first population of particles 18 contained within the pouch. Nor can the nicotinic compound in the cores 19 migrate through the coating 11. However the saliva can contact the cores 15 of the second population of particles 13 due to the absence of the coating 11. This means that the nicotinic compound contained in the cores 15 of the second population of particles 13 can start to solubilise and pass into the oral cavity of the user. When the user desires an additional "hit" of nicotinic compound they bite down or chew on the smokeless article to break the coating 11 of the first population of particles. This exposes a portion of the core 19, such that saliva can contact the core material. A nicotinic compound within the core 19 is then extracted into the saliva and may enter the user's blood stream by oral consumption to provide a "hit" of nicotinic compound.

[0105] Figure 3 shows a third embodiment of a smokeless article 10' having a pouch 12, the pouch being a porous substrate. The pouch 12 contains a content 14 including particles 18 that are formed of a core 19 having a coating 11 of a non-porous, saliva-stable material surrounding the core. The coating 11 is frangible. The pouch 12 also contains a second population of particles 13 that are formed of a core 15 but without the coating of non-porous, saliva-stable material. In some embodiments the second population of particles 13 is absent. The pouch 12 is substantially circular. The pouch 12 is formed from two opposing sheets of a porous substrate and is substantially filled by the content 14. The pouch 12 has a circumferential seal 16 along the edges where the two opposing sheets of a porous substrate meet to seal the contents 14 in the pouch 12.

[0106] Figure 4 shows a fourth embodiment of a smokeless article 10" that, like the second embodiment, has a pouch 12 made from a single sheet of a porous substrate. However, one of the three seals 16' is formed by an overlap of the inner surface and the outer surface of the single sheet of porous substrate to seal the contents 14 in the pouch 12. The remaining two seals at opposing ends of the pouch are formed where the inner surface of the single sheet of porous substrate meets itself. The pouch 12 contains a content 14 including particles 18 that are formed of a core 19 having a coating 11 of a non-porous, saliva-stable material surrounding the core. The coating 11 is frangible. The pouch 12 also contains a second population of particles 13 that are formed of a core 15 but without the coating of non-porous, saliva-stable material. In some embodiments the second population of particles 13 is absent.

[0107] Figure 5 shows a release profile of two embodiments of the present smokeless article which contain only the first population of particles as described herein, i.e. those coated with a non-porous, saliva-stable material, and one smokeless article shown for comparison. In the profile for "Embodiment 1" the smokeless article is inserted into the mouth at time 0 and then chewed once 15 minutes later. The nicotine is then released from the cores of the particles over the following 40 minutes (up to 55 minutes after the article was inserted into the mouth). In the profile for "Embodiment 2" the smokeless article is inserted into the mouth at time 0 and then chewed three times at 5 minutes, 25 minutes, and 40 minutes. The nicotine is released from a different subset of the particles after each chew. The release profile of a standard uncoated tobacco snus is shown for comparison.

[0108] Figure 6 shows a release profile of two embod-

iments of the present smokeless article each containing both a first and second population of particles as described herein, and one smokeless article shown for comparison. In the first embodiment ("25% coated") 25 wt.% of the nicotinic compound in the article is present in a first population of particles as described herein and 75 wt.% of the nicotinic compound in the article is present in a second population of particles as described herein. The release profile shows an initial nicotine release from the second population of particles followed by a user chewing the article at 9 minutes after insertion into the mouth which initiates a further release of nicotine from the first population of particles.

[0109] In the second embodiment ("50% coated") 50 wt.% of the nicotinic compound in the article is present in a first population of particles as described herein and 50 wt.% of the nicotinic compound in the article is present in a second population of particles as described herein. The release profile shows an initial nicotine release from the second population of particles followed by a user chewing the article at 9 minutes after insertion into the mouth which initiates a further release of nicotine from the first population of particles. A second chew at 25 minutes after insertion into the mouth initiates another release of nicotine from particles in the first population for which the first chew by the user did not fracture the coating.

[0110] The comparison release profile ("100% coated") shows no initial nicotine release due to all of the available nicotine being contained in particles having a non-porous, saliva-stable coating. The chew by the user at 9 minutes after insertion into the mouth then initiates release of the nicotine in a similar way to that of the first embodiment.

[0111] The features disclosed in the foregoing description, or in the following claims, or in the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for obtaining the disclosed results, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

[0112] While the invention has been described in conjunction with the exemplary embodiments described above, many equivalent modifications and variations will be apparent to those skilled in the art when given this disclosure. Accordingly, the exemplary embodiments of the invention set forth above are considered to be illustrative and not limiting. Various changes to the described embodiments may be made without departing from the scope of the invention.

[0113] For the avoidance of any doubt, any theoretical explanations provided herein are provided for the purposes of improving the understanding of a reader. The inventors do not wish to be bound by any of these theoretical explanations.

[0114] Any section headings used herein are for organizational purposes only and are not to be construed as limiting the subject matter described.

[0115] Throughout this specification, including the claims which follow, unless the context requires otherwise, the words "have", "comprise", and "include", and variations such as "having", "comprises", "comprising", and "including" will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[0116] It must be noted that, as used in the specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" one particular value, and/or to "about" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by the use of the antecedent "about," it will be understood that the particular value forms another embodiment. The term "about" in relation to a numerical value is optional and means, for example, +/- 10%.

[0117] The words "preferred" and "preferably" are used herein refer to embodiments of the invention that may provide certain benefits under some circumstances. It is to be appreciated, however, that other embodiments may also be preferred under the same or different circumstances. The recitation of one or more preferred embodiments therefore does not mean or imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the disclosure, or from the scope of the claims.

Claims

1. A smokeless article for oral consumption comprising a pouch containing a first particle population comprising a plurality of particles; in the first particle population the particles comprise a core comprising a nicotinic compound, wherein the core is encapsulated by a continuous coating of a non-porous, saliva-stable material, and wherein the coating is frangible, such that in use the coating fractures on chewing.

2. The smokeless article of claim 1, wherein the pouch further comprises a second particle population comprising a plurality of particles; in the second population the particles comprise a core comprising a nicotinic compound, wherein the nicotinic compound is releasable on exposure of the second particle population to saliva.

3. The smokeless article of claim 2, wherein about 20 wt.%, about 25 wt.%, about 50 wt.%, about 75 wt.%, about 80 wt.% or about 90 wt.% of the total amount of nicotinic compound in the smokeless article is present as the nicotinic compound in the first particle

population.

4. The smokeless article of any one of claims 2 or 3, wherein at least about 10 wt.% of total amount of nicotinic compound in the smokeless article is present in the second particle population.

5. The smokeless article of any preceding claim, wherein all of the nicotinic compound in the smokeless article is contained in the cores of the particles.

6. The smokeless article of any preceding claim, wherein the nicotinic compound is selected from nicotine, nicotine salt(s), nicotine complex(es); and nicotine solvate(s).

7. The smokeless article of any preceding claim, wherein the nicotinic compound is provided in a plant material.

8. The smokeless article of claim 7, wherein the plant material is tobacco.

9. The smokeless article of any one of claims 1 to 7, wherein the pouch contents is tobacco-free.

10. The smokeless article of any preceding claim, wherein the non-porous, saliva-stable material is a polymer, or is selected from sorbitol, maltitol, isomalt, mannitol, starch, gelatin, gum arabic, polyvinyl acetate, carob bean gum, refined paraffin wax, shellac, locust bean gum, petroleum wax, terpene resin, tragacanth, polyethylene, xanthan gum, and combinations thereof.

11. The smokeless article of any preceding claim, wherein the non-porous, saliva-stable material is hydrophobic.

12. A method of manufacturing a smokeless article for oral consumption, the method comprising:

(i) forming a first population of particles by applying a coating material to encapsulate each of a plurality of cores each core comprising a nicotinic compound, the coating being a continuous coating of a non-porous, saliva-stable material; wherein the coating is frangible;
(ii) forming a porous pouch containing the first population of particles;
(iii) optionally forming a second population of particles each core comprising a nicotinic compound which is releasable on exposure of the second particle population to saliva and incorporating the second population of particles into the porous pouch in a predetermined ratio with the first population of particles; and
(iv) thermally or chemically sealing the pouch to enclose the population(s) of particles.

13. A smokeless article for oral consumption produced by a process according to claim 12.

14. A kit comprising a plurality of smokeless articles according to any one of claims 1 to 11 and/or 13 and a container.

15. Use of the smokeless article according to any of claims 1 to 11 and/or 13 as a smoking substitute device.

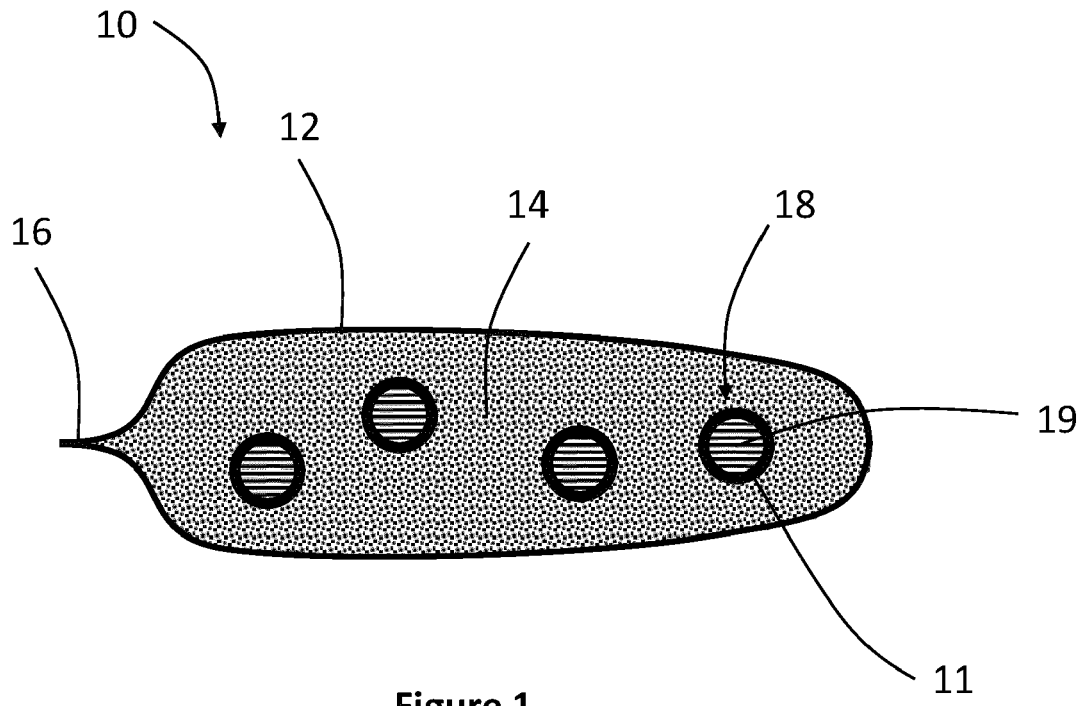

Figure 1

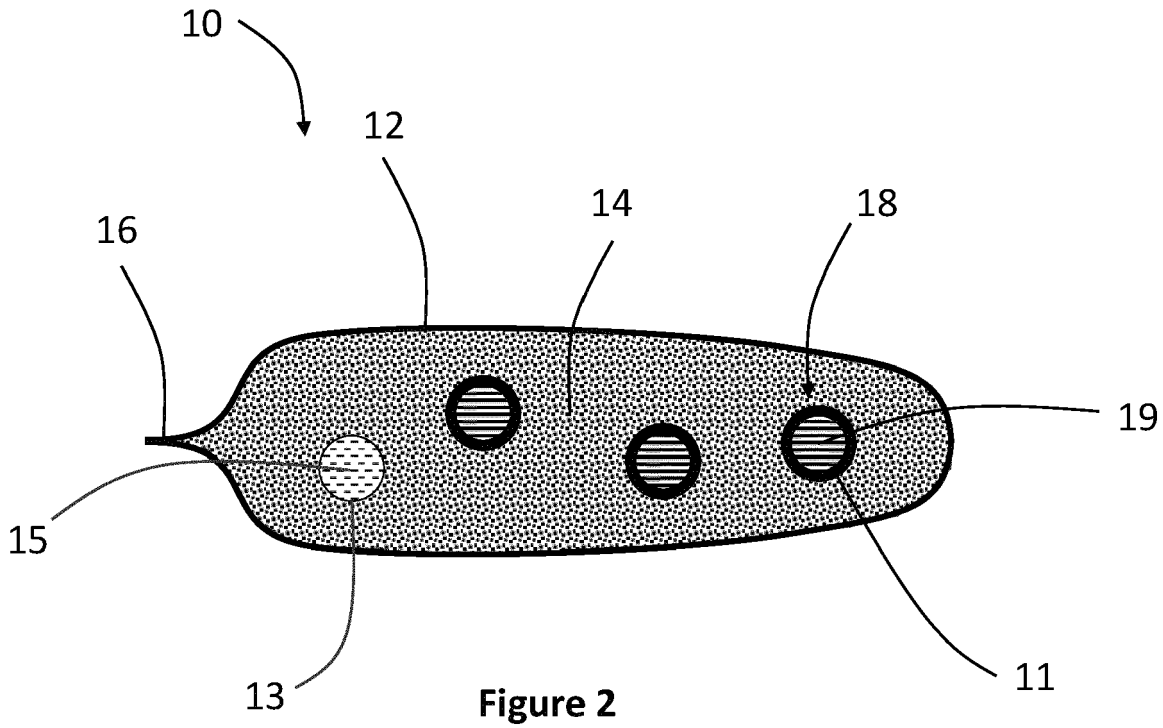

Figure 2

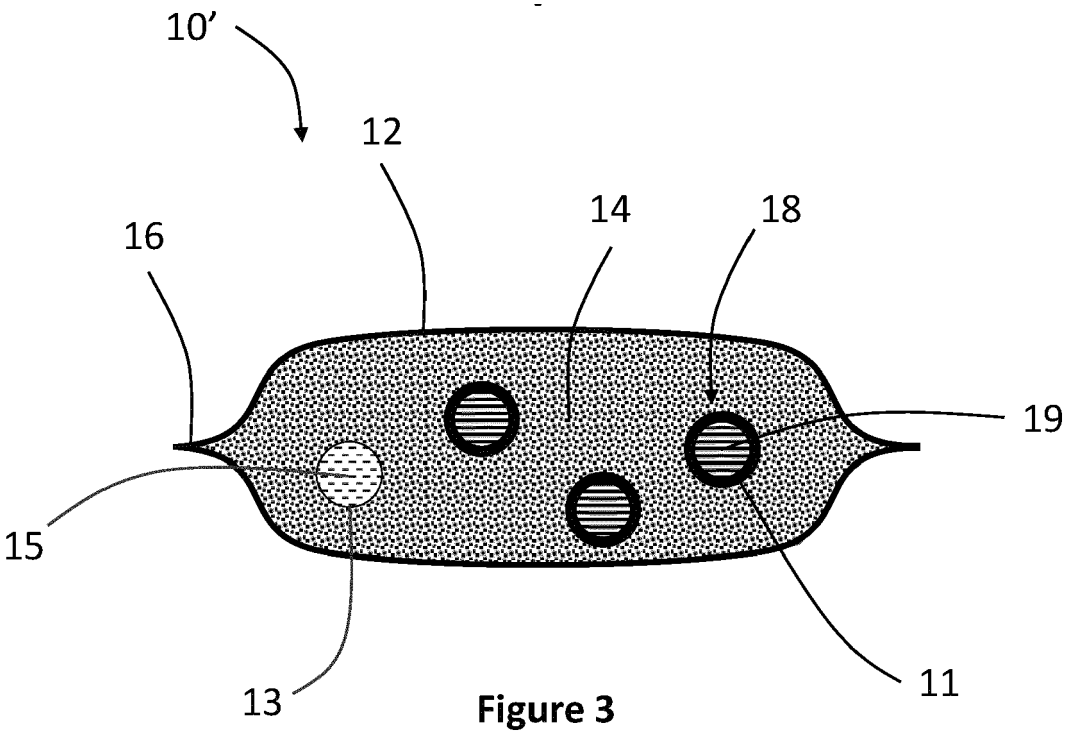

Figure 3

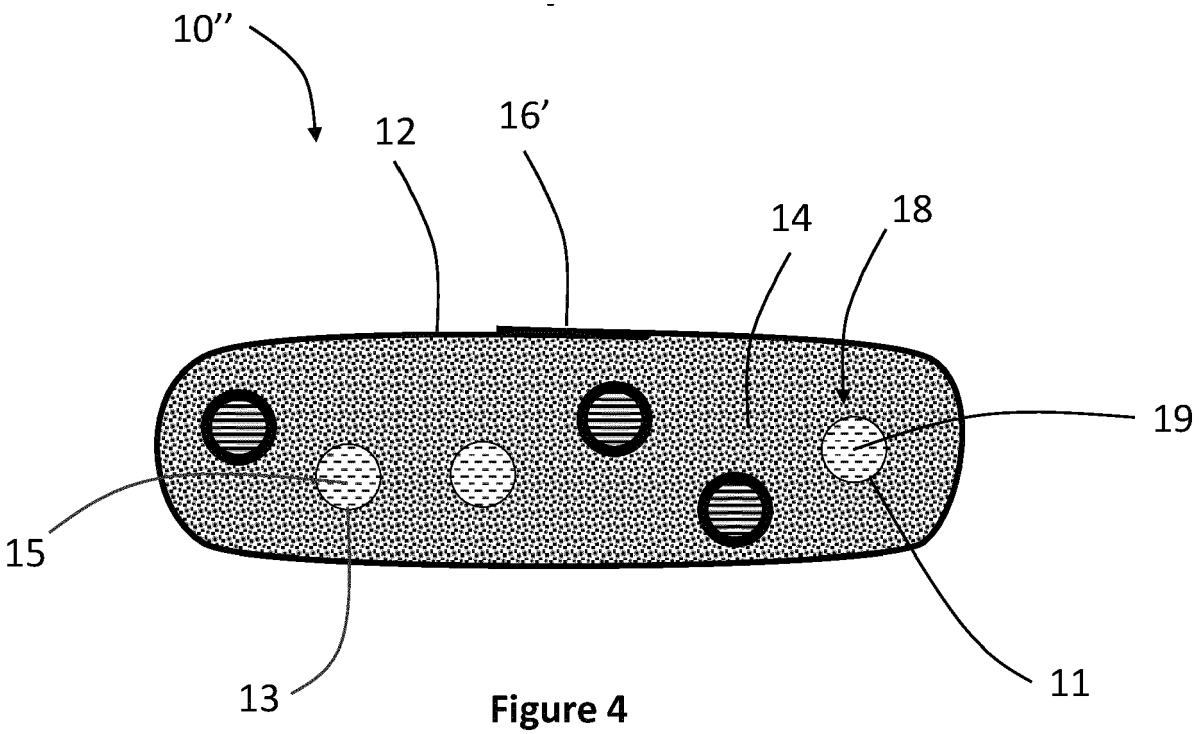

Figure 4

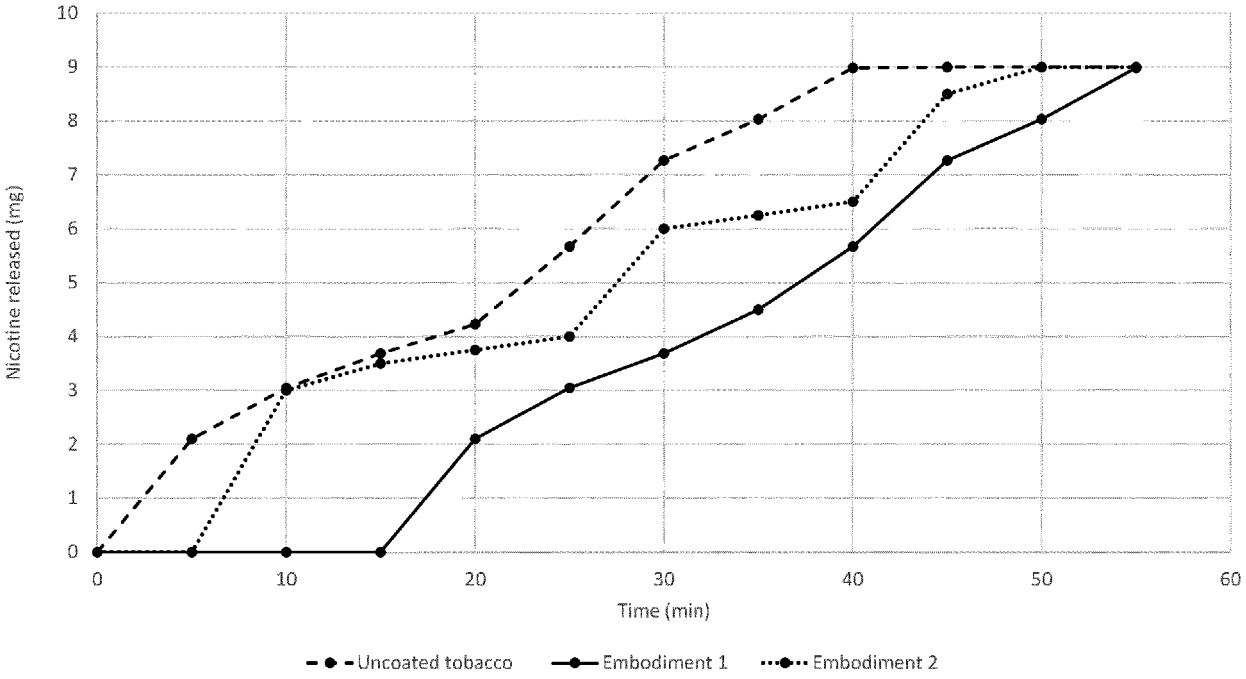
Nicotine released (mg)
0
1
2
3
4
5
6
7
8
9
10
0
10
20
30
40
50
60
Time (min)
Uncoated tobacco
Embodiment 1
Embodiment 2

Figure 5

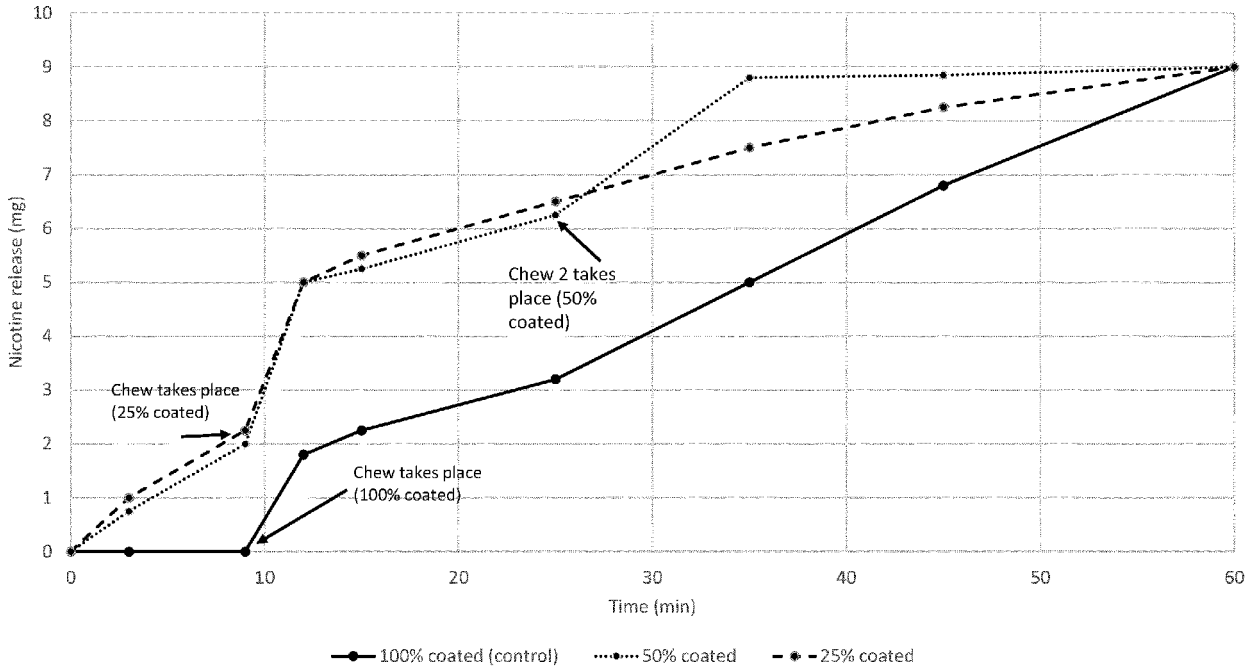
Nicotine release (mg)
Time (min)
Chew takes place (25% coated)
Chew takes place (100% coated)
Chew 2 takes place (50% coated)
100% coated (control)
50% coated
25% coated

Figure 6

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EUROPEAN SEARCH REPORT

Application Number
EP 19 21 7705

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	23 June 2020	Villányi Kelemen, K

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X : particularly relevant if taken alone
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L : document cited for other reasons

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23-06-2020

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 2017044558 A1	16-03-2017

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REFERENCES CITED IN THE DESCRIPTION

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