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(54) **NICOTINE COMPOSITION**

(57) The present invention describes a composition, such as a tobacco free or low tobacco nicotine containing composition, comprising:

- From about 0.2wt% to about 2wt% nicotine in free base form;
- a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- water in an amount at least 35 wt%;

d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;

e. a release control agent comprising agar agar in an amount from about 0.1wt% to about 2 wt%

f. optional additional ingredients, preferably in an amount up to about 12 wt%.

The composition may be provided in pouches for oral delivery to a user.

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Description

[0001] The present invention relates to tobacco-free or low-tobacco nicotine compositions. The compositions are preferably for human consumption, such as may be delivered orally by means of placing a permeable pouch filled with the compositions in the mouth of a user.

[0002] Nicotine-loaded tobacco-free or low-tobacco pouches are replacement products that can help to alleviate cravings associated with smoking cigarettes, cigars, or other nicotine delivery products. When smoking cigarettes or using nicotine-delivery systems based on inhalation, i.e., so-called vaping, nicotine vapor is quickly absorbed through the lungs into the blood stream, reaching the brain within ten seconds of inhalation. The latter produces a feeling of almost instantaneous satisfaction, that lasts also some time after smoking/inhalation.

[0003] Nicotine-loaded tobacco-free or low-tobacco pouches are intended for use in the mouth by placing the pouch under the lip, thereby enabling the release and absorption of nicotine through oral mucosa. The pouches typically comprise a saliva permeable membrane material and contain particulate filler materials, nicotine or nicotine derivatives and other ingredients such as flavourings. The particulate materials may comprise *inter alia* polysaccharide or cellulose materials.

[0004] Nicotine is an alkaloid, which was traditionally derived from tobacco leaves but may now also be provided in a fully synthetic form. It is available both as a free-base nicotine and in the form of different nicotine salts that are produced from the interaction between nicotine and an acid. Common nicotine salts include chloride, sulfate, benzoate, tartrate salts.

[0005] It is known to provide tobacco-free or low-tobacco pouches where nicotine is provided in salt form in a powder formulation. The provision of nicotine salts in such formulations is deployed in part because of the high degree of stability of the system toward chemical degradation and/or evaporation.

[0006] In order to provide the egress of free base nicotine from formulations involving nicotine salts, the formulations contain significant quantities of buffering salts to increase the alkalinity of the formulation. Increased alkalinity shifts the dissociation constant of the nicotine such that the free base form is made in solution (such as in the mouth of the user) from the ionic form of nicotine in the salts. The uncharged free-base nicotine exhibits enhanced permeability across the oral mucosa into the blood stream compared to its ionic form, which is critical for consumer use.

[0007] In particular, the pH of nicotine-loaded tobacco-free pouches ranges typically between 6.9 and 10.1, which translates into undissociated free-base nicotine levels between 7.7 to 99.2 %, respectively (Stanfil et al. Nicotine & Tobacco Research, 2021, 1590-1596).

[0008] It follows that nicotine salt formulations tend to feature a low moisture content, i.e. less than 10wt%. (such as 1-8 wt%). This is because higher moisture content would stimulate the formation of free base nicotine *in situ*, which would in turn reduce the stability of the product because free base nicotine is volatile and labile to oxidative degradation. When nicotine oxidises it produces a yellow-brown coloration which is often unappealing to consumers and also produces an unpleasant taste. Indeed, some formulations involve large quantities of sweetener (such as maltitol) to stimulate salivation. However the overproduction of saliva tends to result in users spitting or swallowing, impacting nicotine uptake. Moreover, degradation of the product is indicative of reactivity in the system which may result in the presence of undesired (and potentially toxic) compounds.

[0009] These requirements provide problems for the user. Formulations which have low moisture content can feel hard and unpalatable when in use, while high alkalinity (especially a pH greater than about 9) can be irritating to the gums of the user. In contrast, moist nicotine products show enhanced palatability, i.e., soft and pleasant mouthfeel, when used in the mouth.

[0010] Nicotine loaded pouches containing free-base nicotine products have been provided with moisture levels on upwards of 35 wt%. However, formulations of this type require stabilization to act against degradation of the nicotine and also require components to prevent moisture loss upon storage. As such, moist free base nicotine products tend to require the use of a greater number and quantity of additives than those containing nicotine salts.

[0011] WO 2010/104464 and WO 2010/0114445 disclose compositions of free-base nicotine that can be stabilized using a salt of alginic acid, such as sodium alginate (e.g., Protanal LFR 5/60). The amount of sodium alginate used as a stabilizer is substantial, typically corresponding to nicotine:Protanal 1:2 ratio (wt). WO2020244721 discloses a composition of free-base nicotine wherein the latter is stabilized using an ion exchange resin, e.g., polacrilex resin, such as Amberlite IRP64 (methacrylic acid polymer with divinylbenzene, or potassium salt of the latter). The amount of polacrilex resin used as a nicotine stabilizer is in a nicotine-to-resin ratio which may vary between 1:1.19 and 1:4. It is to be understood that polymers having some carboxylate groups are typically used to stabilise free-base nicotine.

[0012] To prevent the loss of moisture in free-base nicotine formulations upon storage, it is common to use humectants such as sugar alcohols. US 2020/0383372 discloses several compositions of free-base nicotine with polacrilex resin having a moisture content above 15%, most commonly around 30%. The humectants of choice include sugar alcohols from glycerol, propylene glycol, polyethylene glycol, alginate, pectin, xanthan gum, modified starch, hydroxypropyl cellulose, and triacetin.

[0013] However, the moisture present in the product poses significant challenges for formulation. Moisture acts not only as a nicotine solvent that facilitates diffusive transport from formulation to the oral mucosa but also a medium for chemical

reactions that can significantly accelerate the rate of chemical degradation and product spoilage. Indeed, high moisture content nicotine formulations may still be unstable, especially if the moisture content exceeds 30% wt. As described above, degradation of nicotine causes discoloration of the product. Furthermore, it is important to avoid nicotine degradation and to prevent moisture evaporation during storage, which may cause discrepancy between the factual and stated nicotine loading (mg nicotine per g). This reduces the shelf life of the product.

[0014] Physical instability is also a common problem of moist products. Physical instability may include discoloration, stickiness, lumping, phase transitions, such as dissolution-recrystallization and evaporation. Discoloration and chemical degradation may be connected to each other. Lumping of powder may require additional sieving for particle size control after compounding, which results in additional costs during processing.

[0015] The physical and chemical instability may lead to accumulation of toxic by-products of nicotine degradation as well as negative product experiences due to color changes (white product turning yellow, brown, or pink), dusting due to drying and leakage through pouch, product hardening and deteriorated mouthfeel as well as altered nicotine release profile.

[0016] There is therefore a need to provide tobacco-free or low-tobacco nicotine compositions which are suitable for use in pouches and in which the nicotine has a high degree of chemical stability, the composition has a high degree of physical stability, the pH is at a level which is comfortable for the user and which contains a relatively high degree of moisture.

[0017] There is a further need to provide a moist tobacco-free or low-tobacco nicotine composition to provide both fast nicotine release (and thus fast absorption to the blood stream) and to enhance the overall organoleptic experience of the user.

[0018] There is a further need to provide such products which may be produced in a simple, reliable and cost efficient manner.

[0019] In a first aspect, the present invention provides A composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%;
- f. optional additional ingredients, preferably in an amount up to about 12 wt%. All wt% are expressed as a percentage of weight the composition as a whole.

[0020] In a second aspect, the invention provides the use as a nicotine release control agent of agar agar in a composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar in an amount from about 0.1wt% to about 2 wt%;
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

[0021] In a third aspect, the invention provides the use as a nicotine stabilising agent of agar agar in a composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar in an amount from about 0.1wt% to about 2 wt%;
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

[0022] Preferably, the composition further comprises additional ingredients, in an amount from about 1 wt% to about 10 wt% or more preferably in an amount from about 1 wt% to about 8 wt%. The additional ingredients may comprise one or more additives selected from flavourings, flavour enhancers, sweeteners and preservatives.

[0023] Sweeteners are preferably present in an amount from about 1wt% to about 3 wt %. The sweeteners may comprise compounds selected from sugars (such as sucrose, fructose, glucose, dextrose, maltose, lactose, galactose), sugar alcohols (such as xylitol, maltitol, sorbitol, erythritol) and/or sugar substitutes (such as aspartame, saccharin,

sucralose, allulose, acesulfame K, cyclamate or steviol glycosides).

[0024] Preferably, the sweeteners include a sugar alcohol in an amount less than 3 wt%, preferably less than 2 wt%, such as between 1 wt% and 2 wt%. Additionally or alternatively, the sweetener may comprise a sugar substitute in an amount less than 1 wt%, preferably less than 0.5 wt%, such as between 0.05 wt% and 0.3 wt%. Preferred sweeteners include xylitol and/or acesulfame K.

[0025] Preservatives may comprise one or more preservatives selected from calcium chloride, salts of sorbic acid (such as potassium sorbate), salts of benzoic acid (such as sodium benzoate), nitrate salts, nitrite salts, sulfate salts, sulfite salts and propanoate salts. Preferably, preservatives are in an amount less than about 1wt%, preferably between 0.1wt% and 0.5wt%, such as between about 0.25wt% and about 0.35wt%.

[0026] The pH control salts may comprise buffering salts such as carbonate or sesquicarbonate salts; acetate salts, glycinate, acetate, glycinate, gluconate, borate, glycerophosphate or citrate salts; phosphate salts. Preferred is a combination of ammonium chloride and sodium bicarbonate. Where ammonium chloride is present it may be in an amount between 0.05 wt% and 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.15 wt% and 0.25 wt%. Where sodium bicarbonate is present it may be in an amount between less than 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.2 wt% and 0.3 wt%.

[0027] Preferably, the composition contains greater than 40wt% water, for example between 40 wt% and 50 wt% water, preferably between about 44 wt% and about 48 wt% water.

[0028] Preferably, the native cellulose material comprises powdered cellulose and/or microcrystalline cellulose (MCC), with MCC being preferred.

[0029] The release control agent preferably comprises agar agar in an amount less than about 1wt%, preferably less than 0.7wt% of the composition. Indeed, the release control agent may comprise agar agar in an amount from about 0.2 wt% to about 0.7wt%, preferably in an amount from about 0.2wt% to about 0.5wt%.

[0030] The ratio of agar agar to nicotine is preferably less than about 1.3:1. In further preferred embodiments, the ratio of agar agar to nicotine is from about 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1.

[0031] Some embodiments may include tobacco leaf in an amount less than 5 wt%, preferably about 1 wt% to 3 wt%.

[0032] It is preferred that the pH of the composition, as measured by Coresta Method No.69, 2017, is from 6 to 9, preferably from 7 to 9 and more preferably from 7 to 8.5.

[0033] Preferably, any flavour enhancers present are selected from the group comprising sodium chloride, glutamate salts, glycine salts, inosinic acid salts and 5'-ribonucleotide salts. Where sodium chloride is present, it is preferred to be in an amount less than 8 wt%, preferably between 1 wt% and 7 wt% by weight of the composition.

[0034] The composition preferably includes flavouring compounds in an amount less than about 5 wt% of the total composition, for example less than 3 wt% of the composition or between 0.5 wt% and 3 wt% of the composition.

[0035] Preferred quantities of nicotine in the composition are between 0.2wt% and 3 wt%, or between 0.2wt% and 2wt%.

[0036] In some embodiments, the composition may consist essentially of the components described above.

[0037] In another aspect, the invention provides a water or saliva permeable pouch containing a composition as described above. In a still further aspect, the invention provides a package containing a plurality of those pouches.

[0038] In a further aspect, the invention provides a process for forming a nicotine containing composition, such as that which is described above, the process comprising:

- a. combining in a mixer native cellulose material in an amount 40 wt% to 60 wt% of the intended composition with agar agar powder in an amount 0.2 wt% to 2 wt% of the intended composition, thereby to form a precursor composition;
- b. adding water to the precursor composition and mixing at a temperature greater than 50°C;
- c. adding to the precursor composition nicotine in free base form, in an amount 0.2wt% to about 2wt% of the intended final composition, while the temperature is greater than 50°C;
- d. allowing the mixture to cool.

additional water may be added between steps (c) and (d).

[0039] In preferred embodiments, in steps (b) and (c), the mixing of the precursor is at a temperature greater than about 60°C, preferably above about 70°C, preferably above 80°C.

[0040] In step (b) the water may be provided to the precursor at a temperature above about 70°C, preferably above about 80°C. Indeed, in step (b) the water may be provided to the precursor is in the form of steam or vapour.

[0041] Where additional water is added between steps (c) and (d) it may be at a temperature greater than about 70°C, preferably above about 80°C. Indeed, it may be in the form of steam or vapour.

[0042] In some embodiments, the precursor mixture is heated while in the mixer, for example during step (b) and/or (c) and or during or after any addition of water following step (c).

[0043] In some embodiments, further water is added to the composition after step (d).

[0044] In preferred embodiments, any of the following components may be added to the precursor mixture prior to step

(b):

- e. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt% of the intended composition;
- f. additional ingredients, preferably in an amount up to about 12 wt% of the intended composition.

[0045] Agar agar is a dried, hydrophilic, colloidal polysaccharide complex extracted from red algae (Rhodophyceae). The structure is believed to be a complex range of polysaccharide chains having alternating α -(1 $\rightarrow$ 3) and β -(1 $\rightarrow$ 4) linkages. Agar agar can be separated into a natural gelling fraction, agarose, and a sulphated nongelling fraction, agarpectin. Agar agar is soluble in hot water to form a viscous solution but has poor solubility in cold water and ethanol (95%). A 1% w/v aqueous solution forms a stiff jelly on cooling.

[0046] Where the term "tobacco" is used, we mean any part, such as leaves, stems, and stalks, of any member of the genus *Nicotiana*. The tobacco may be whole, shredded, threshed, cut, ground, cured, aged, fermented, or treated otherwise, e.g., granulated or encapsulated.

[0047] Embodiments of the present invention will now be described with reference to the following drawings:

Figure 1 shows a plot of nicotine release profiles for a composition according to the present invention and comparative examples;

Figure 2 shows a plot of nicotine release profiles for a composition according to the present invention and comparative examples;

Figure 3 shows photographs of a pouch and composition according to the present invention and comparative examples.

[0048] In a first embodiment of the present invention there is provided a tobacco free (or in some instances low tobacco) nicotine formulation for use in pouches for oral use. The formulation has a high water content and contains nicotine in its free base form. The composition involves a cellulosic filler and also the use of agar agar as a nicotine release agent to promote the release of nicotine from the composition when it is placed (e.g. in a pouch) in the oral cavity of a user.

[0049] In an embodiment, the composition has a general formulation as described below:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. A native cellulose material, such as microcrystalline cellulose, in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts, such as a combination of ammonium chloride and sodium bicarbonate in an amount from about 1 wt% to about 6 wt%;
- e. a release control agent comprising agar agar or a derivative thereof in an amount from about 0.1wt% to about 2 wt%;
- f. optional additional ingredients, such as flavourings, flavour enhancers, sweeteners and preservatives, preferably in an amount up to about 12 wt%.

[0050] All wt% are based on the total weight of the composition.

[0051] The quantity of nicotine in the composition varies by the desired strength of the product. In some embodiments the quantity of nicotine is between 0.2wt% and 3 wt%, or between 0.2wt% and 2wt%.

[0052] The native cellulose useful in the present invention may comprise powdered cellulose and/or microcrystalline cellulose. Examples of powdered cellulose which may be used in the invention include Arbocel(RTM) as supplied by J. Rettenmaier & Söhne GmbH; Elcema; KC Flock(RTM) supplied by Nippon Paper Industries Co. Ltd.; Microcel 3E-150 supplied by Roquette Frères; Sanacel (RTM) supplied by CFF GmbH; Sanacel Pharma (RTM) supplied by CFF GmbH; Sancel-W supplied by NB Entrepreneurs Company; or Solka-Floc (RTM) supplied by J. Rettenmaier USA LP.

[0053] Examples of microcrystalline cellulose which may be used in the invention include Avicel (RTM) PH supplied by Dupont Nutrition and Biosciences, Inc.; Cellets (RTM) supplied by Pharmatrans Sanaq AG; Celphere (TM) supplied by Asahi Kasei Corporation; Ceolus (TM) KG supplied by Asahi Kasei Corporation; Emcocel (RTM) supplied by JRS Pharma GmbH; MCC Sanaq (RTM) supplied by Pharmatrans Sanaq AG; Pharmacel (RTM) supplied by DFE Pharma GmbH; Tabulose (RTM) supplied by Roquette Frères; Vivapur (RTM) supplied by JRS Pharma GmbH.

[0054] While the water content of the composition should be at least 35wt%, it is preferred that a greater proportion of water is contained in the composition. Greater palatability for the user, including greater softness, tends to be found when the water content of the composition is greater than 40 wt%. Preferred compositions have a water content greater than 42 wt%, for example between 44 wt% and 48 wt% water.

[0055] The composition contains pH control salts to provide optimum pH of the composition while in use in the mouth of a user. It is preferred that the pH of the composition, when measured according to the Coresta Method No.69, 2017, is from 6 to 9, preferably from 7 to 9 and more preferably from 7 to 8.5. This can be achieved by providing pH adjusting agents such as sodium bicarbonate or buffering salts such as a combination of an ammonium chloride and sodium bicarbonate. Typical

quantities of pH control salts are between 0.2wt% and 2wt%, preferably between 0.2 wt% and 1 wt%. Alternative buffering salts may be selected from e.g. carbonate or sesquicarbonate salts; acetate salts, glycinate, acetate, glycinate, gluconate, borate, glycerophosphate or citrate salts; phosphate salts.

[0056] Flavourings contained within the composition are not limited but preferably include flavonoid compounds to stimulate the olfactory system of the user, typically in an amount of less than about 3wt% of the total composition. Such compounds are commercially available and are well known to those skilled in the art.

[0057] The flavour of the composition may be improved by the inclusion of sweeteners or flavour enhancers.

[0058] Sweeteners may include sugar based sweeteners such as sucrose, fructose, glucose, dextrose, maltose, lactose, galactose; sugar alcohols such as xylitol, maltitol, sorbitol, erythritol; or other sugar substitutes such as aspartame, saccharin, sucralose, allulose, acesulfame K, cyclamate or steviol glycosides. The sweeteners may be present alone though are preferably used in combination (for example a sugar alcohol and a sugar substitute). A preferred combination is xylitol and acesulfame K. Quantities of the sweetener present in the composition depend on the properties of the sweeteners chosen, as would be understood by a person skilled in the art but typically range between 1 wt% and 3 wt% in total.

[0059] Flavour enhancers may include sodium chloride, salts of glutamic acid (such as sodium glutamate), glycine salts, inosinic acid salts and 5'-ribonucleotide salts (such as on or more disodium ribonucleotides). Quantities of the flavour enhancer present in the composition depend on the properties of the flavour enhancer chosen, as would be understood by a person skilled in the art but typically range between 1 wt% and 8 wt% in total.

[0060] Preservatives may include antimicrobial preservatives such as sorbic acid salts (such as sodium or potassium sorbate), benzoic acid salts, nitrate salts, nitrite salts, sulfate salts, sulfite salts and propanoate salts. Salts such as calcium chloride may also be used as preservatives.

[0061] All compositions may contain a small quantity of tobacco, such as between 1 wt% and 5 wt%, especially when contained in a pouch.

[0062] The inventors have surprisingly found that the presence of agar agar in the composition acts as an effective nicotine stabilizer and release control agent. Without wishing to be bound by any particular theory, it is postulated that the nicotine may be partially bound within an agar agar gel which may be formed during manufacture. This appears to provide both a highly stable nicotine composition, which despite the use of free base nicotine and high levels of moisture is able to maintain a long shelf life. Moreover, the nicotine release profile of the composition is fast and consistent, providing excellent product performance.

[0063] This performance is provided despite a relatively small quantity of agar agar being provided in the composition. The agar agar is preferably present in an amount from 0.1wt% to about 1.2 wt%. It is preferably present in a ratio of agar agar to nicotine of 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1. This is a significantly lower ratio than would be required for prior art stabilizing agents.

[0064] Any food or pharmaceutical grade agar agar may be utilized in the present invention. Specific examples include Rokoagar (RTM) RGM 600 and RGM 800, as supplied by Industrias Roko, S.A..

[0065] In preferred embodiments, the composition may have a general composition as follows:

- a. From about 0.2wt% to about 3wt% nicotine in free base form;
- b. Microcrystalline cellulose, in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt% and preferably above 40 wt%;
- d. buffer salts ammonium chloride in an amount 0.05 wt% and 1wt% and sodium bicarbonate in an amount from about 0.1 wt% to about 1 wt%;
- e. a release control agent comprising agar agar in an amount from about 0.1wt% to about 2 wt%
- f. optional additional ingredients, such as
 - a. flavourings in an amount from 0.5 wt% to about 3 wt%,
 - b. flavour enhancers such as sodium chloride in an amount between 2wt% and 8wt%,
 - c. sweeteners such as xylitol in an amount from about between 1 wt% and 2 wt% and/or acesulfame K in an amount from 0.05 wt% to 1 wt%; and
 - d. preservatives, such as potassium sorbate in an amount from about 0.25 wt% to about 1 wt%.
 - e. tobacco in a quantity from 0 wt% to 3 wt%.

[0066] In a further embodiment, there is provided a process for the manufacture of tobacco-free or low-tobacco nicotine compositions. The process involves the mixing in a vessel (such as an autoclave) the native cellulose in a portion of from 30 wt% to 60 wt% of the intended final composition and agar agar in a portion of from 0.1 wt% to 2 wt% of the final composition, each in powder or granular form. One or more of the other solid components of the composition, such as pH control salts, flavour enhancers, sweeteners or preservatives may also be added at this stage of the process, though any tobacco intended for inclusion in the final composition should ideally be held until the remainder of the composition is complete.

[0067] At least a portion of the water (preferably at least 10wt% of the intended final composition) is then added to the composition and the composition is heated. The heating may take place in a number of ways. The mixing vessel may be heated, for example by use of a heating manifold. Alternatively or additionally, the water may be heated prior to its introduction to the mixing vessel or some or all of the water may be added as steam.

[0068] The temperature of the resulting precursor mixture should be at least 50°C, preferably at least 60°C and more preferably at least 70°C. The precursor is heated such that the agar agar at least partially dissolves in the water. Without wishing to be bound by any theory, it is postulated that the low concentration of agar agar coupled with shear applied during mixing, sufficient dissolution of agar agar may be obtained at such temperatures.

[0069] While the heated precursor mixture is being mixed, the nicotine is added to the precursor in an amount from 0.2 wt% to 2 wt% of the final composition. At this stage, other liquid components of the composition, such as flavourings, may be added.

[0070] Optionally, a second portion of water (preferably at least 10wt% of the intended final composition) is then added to the composition and the composition is heated, again to at least 50°C, preferably at least 60°C and more preferably at least 70°C.

[0071] The precursor is then allowed to cool, preferably while mixing is continued. The resulting composition may be set aside. Without wishing to be bound by any particular theory, it is believed that the agar agar forms a gel which at least partially encapsulates the nicotine which is present, stabilizing it and also providing excellent release properties.

[0072] In an optional finishing step, the resulting composition may have further water added to it, preferably with the water at ambient temperature. This step is to afford a greater content to the composition where required. In some embodiments, flavour enhancers, sweeteners or preservatives may be added at this stage, additionally to or in the alternative to their addition earlier in the process.

[0073] The finished composition may optionally be mixed with tobacco in an amount of up to 5 wt% of the final composition. The composition is soft to the touch, produces little dust and does not form clumps. The product is white in colour. In preferred embodiments, it is packed into saliva permeable pouches ready for oral delivery.

Examples

[0074] A number of compositions were produced according to the method described above.

	Example 1	Comparative Example 1	Comparative Example 2
Ingredient	w/w (%)		
Water	46%	46%	46%
MCC	42,13%	24,50%	41,80%
Sodium chloride	5,30%	4,00%	6,00%
Aromas	3%	1.59%	3.8%
Xylitol	1,72%	1,80%	0,50%
Nicotine	0,60%	0,60%	0,60%
Agar Agar	0,30%	20%	-
Potassium Sorbate	0,30%	0,30%	0,20%
Acesulfam K	0,20%	0,15%	0,15%
Ammonium chloride	0,20%	0,10%	0,60%
Sodium bicarbonate	0,25%	0,26%	0,35%

[0075] 0.7g portions of each of the finished compositions were packed into a saliva permeable pouch and tested according to the following release test:

A single person avoids nicotine intake for 10 hours before the experiment starts and avoids food or drink intake 1 hour before the experiment starts. Prior to the procedure, the testing person rinses his or her mouth with water and waits for 10 minutes.

[0076] A pouch is taken and the weight is measured before being placed under the lip of the testing person. The pouch is kept in place, without moving, for 5 minutes. The pouch is then removed and placed in a 50cm³ distilled water and stirred or shaken for 30 minutes. A sample is taken and analysed for its nicotine content using HPLC.

[0077] The tester then waits at least one hour before repeating the experiment, holding the pouch in place for 10, 20, 30

and 40 minutes on successive repeats.

[0078] The results of the release tests are plotted in Figure 1. As can be seen, a slight increase in the release rate and total release of nicotine over 40 minutes can be seen with the inclusion of 20 wt% agar agar. However, as can be surprisingly seen, a relatively small proportion of agar agar in the composition (0.3 wt%, with 0.6 wt% nicotine) provides a very significant increase in both release rate and total release over 40 minutes.

[0079] Further compositions, identical to those of Example 1 but which comprised different stabilizers in place of agar agar were prepared and tested according to the same method. The stabilizers used in these examples are shown in the table below:

Example	Stabilizer
Comparative Example 3	Sodium Alginate
Comparative Example 4	Sodium carboxymethyl cellulose
Comparative Example 5	Chitosan
Comparative Example 6	Pectin
Comparative Example 7	Methyl cellulose
Comparative Example 8	Guargum
Comparative Example 9	Vegetable oil-glycerol (2:1)

[0080] The results of the release tests are plotted in the graph at Figure 2, with the plot of Example 1 overlaid. It is clear from the plot that agar agar provides for the greatest overall release of nicotine over a 40 minute period and also provides for a significantly faster release over the first 10 minutes of use. This provides significant advantages for users seeking to cease smoking.

pH Test - Corresta Method No. 69, 2017

[0081] A pH electrode is calibrated using at least two pH buffers (4,00 and 7,00 or 7,00 and 10,00) to produce a two-point calibration that will cover the pH range of the products tested. Calibration is performed in conjunction with the measurements of the samples and at 23°C. The calibration slope must be within 95 % - 105 % before the electrode can be used for sample measurements. The electrode must be rinsed, before and after each measurement, with water.

[0082] The samples for testing are allowed to reach room temperature before preparation. Samples are then mixed with water at a concentration of 5 wt% and shaken or stirred for 30 minutes. The pH electrode is then used to determine the pH of the water in the sample mixture.

Comparative Examples 10 to 12

[0083] Comparative examples 10-12 list commercial products which are based on a nicotine salt and featuring low moisture content, i.e., below 10% wt. These products generally feature long shelf life of at least 12 months. However, discoloration and lumpiness increase with increasing moisture content. Very dry products may dust during storage and be difficult to handle during packaging. Low moisture products typically feature poor palatability (dry mouthfeel) and show delayed nicotine release. The appearance of samples is presented in Figure 3.

Comparative Example 10

[0084]

Composition	Characteristics
Nicotine	Nicotine content: 16.6 mg/g
MCC	Moisture content: 5.94%
Maltitol	Shelf-life: 15 months
Sodium bicarbonate	Color (storage): White
Aromas	Lumping: No

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(continued)

Composition	Characteristics
Glycerol	Palatability: Poor
Polyvinylpyrrolidone	Release: Slow
Acesulfame K	Dusting: Yes
	pH: 8.71

Comparative Example 11

[0085]

Composition	Characteristics
Nicotine	Nicotine content: 15 mg/g
MCC	Moisture content: 4.79%
Maltitol	Shelf-life: 12 months
Hydroxypropyl cellulose	Color (storage): White
Sodium bicarbonate	Lumping: No
Acesulfame K	Palatability: Poor
Aromas	Release: Slow
	Dusting: Yes
	pH: 8.39

Comparative Example 12

[0086]

Composition	Characteristics
Nicotine	Nicotine content: 17 mg/g
MCC	Moisture content: 8.31%
Maltitol	Shelf-life: 10 months
Chewing gum base	Color (storage): Creamy white
Sodium bicarbonate	Lumping: Moderate
Glycerol	Palatability: Poor
Propylene Glycol	Release: Slow
Aromas	Dusting: Yes
	pH: 9.61

Comparative Examples 13 to 17

[0087] Comparative examples 13-17 list commercial products based on a nicotine free-base and featuring high moisture content, i.e., above 40% wt. Lumpiness and various degrees of discoloration are characteristic to nearly all products. Comparative Examples 13 to 16 are variations of the same product from the same manufacturer, that vary mainly with respect to aromas, release modifiers, and sweeteners used. The products in these examples contain calcium chloride. Typically, calcium chloride is used as excipient with water binding properties and as antimicrobial preservative. The appearance of samples is presented in Figure 3.

Comparative Example 13

[0088]

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Composition	Characteristics
Nicotine	Nicotine content: 14 mg/g
Water	Moisture content: 44.89%
MCC	Shelf-life: 12 months
Plant fiber	Color (storage): Creamy-Yellowish
Glycerol	Lumping: Visible
Sodium bicarbonate	Palatability: Good
Calcium Chloride	Release: Fast
Sodium Chloride	Dusting: No
Aromas	pH: 8.65
Mono/diglycerides of fatty acids	
Acesulfame K	

Comparative Example 14

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[0089]

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Composition	Characteristics
Nicotine	Nicotine content: 14 mg/g
Water	Moisture content: 44.89%
MCC	Shelf-life: 12 months
Plant fiber	Color (storage): Creamy-Yellowish
Glycerol	Lumping: Visible
Sodium bicarbonate	Palatability: Good
Calcium Chloride	Release: Fast
Sodium Chloride	Dusting: No
Aromas	pH: 8.7
Mono/diglycerides of fatty acids	
Acesulfame K	

Comparative Example 15

[0090]

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Composition	Characteristics
Nicotine	Nicotine content: 14 mg/g
Water	Moisture content: 44.89%
MCC	Shelf-life: 10 months
Plant fiber	Color (storage): Creamy-Yellowish
Glycerol	Lumping: Visible

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(continued)

Composition	Characteristics
Sodium bicarbonate	Palatability: Good
Calcium Chloride	Release: Fast
Sodium Chloride	Dusting: No
Aromas	pH: 9.12
Mono-/diglycerides of fatty acids	
Saccharine	

Comparative Example 16

[0091]

Composition	Characteristics
Nicotine	Nicotine content: 8 mg/g
Water	Moisture content: 41.86%
MCC	Shelf-life: 12 months
Plant fiber	Color (storage): Creamy-Yellowish
Glycerol	Lumping: Visible
Sodium bicarbonate	Palatability: Good
Calcium Chloride	Release: Fast
Sodium Chloride	Dusting: No
Aromas	pH: 8.4

Comparative Example 17

[0092]

Composition	Characteristics
Nicotine	Nicotine content: 14 mg/g
Water	Moisture content: 49.70 %
MCC	Shelf-life: 12 months
Xylitol	Color (storage): White
Glycerol	Lumping: No
Sodium bicarbonate	Palatability: Good
Sodium alginate	Release: Fast
Ammonium chloride	Dusting: No
Sodium chloride	pH: 8.92
Aromas	
Acesulfame K	

Comparative Examples 18 and 19

[0093] Comparative examples 18 and 19 list commercial products based on free-base nicotine and featuring medium

moisture content, i.e., below 10-30% wt. These products feature a shelf life of around 6-12 months. Both products exhibit signs of discoloration and lumpiness. Comparative Example 16, rich in sugar alcohol, is especially prone to form lumps, which harden over time, thereby significantly decreasing product palatability. The appearance of samples is presented in Figure 3.

Comparative Example 18

[0094]

Composition	Characteristics
Nicotine	Nicotine content: 15 mg/g
Water	Moisture content: 29.56 %
Fiber	Shelf-life: 12 months
Xylitol	Color (storage): Yellow-Brownish
Erythritol	Lumping: Strong
Sodium bicarbonate	Palatability: Poor
Sodium alginate	Release:
Potassium sorbate	Dusting: No
Sodium chloride	pH: 9.94
Aromas	
Acesulfame K	

Comparative Example 19

[0095]

Composition	Characteristics
Nicotine	Nicotine content: 13 mg/g
Water	Moisture content: 16.65 %
Plant fiber	Shelf-life: 6 months
Xylitol	Color (storage): White
Glycerol	Lumping: Moderate
Sodium bicarbonate	Palatability: Good
Sodium alginate	Release:
Ammonium chloride	Dusting: No
Sodium chloride	pH: 8.8
Aromas	
Acesulfame K	

EXAMPLE 2

[0096] Example 2 represent an example of formulation according to the present invention. The product features high moisture content and high nicotine stability during at least 12 months of storage. No signs of discoloration, lumping or dusting are observed after storage.

Example 2

[0097]

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Components	w/w%	Characteristics
Nicotine (free-base)	0.8 wt%	Nicotine content: 8 mg/g
Water	45 wt%	Moisture content: 45 %
MCC	42.2 wt%	Shelf-life: 12 months
Agar agar	0.3 wt%	Color (storage): White
Sodium bicarbonate	0.25 wt%	Lumping: No
Ammonium chloride	0.2 wt%	Palatability: Good
Sodium chloride	5.3 wt%	Release: Fast
Aromas	2.75 wt%	Dusting: No
Xylitol	1.7 wt%	pH: 8.5
Potassium Sorbate	0.3 wt%	
Acesulfame K	0.2 wt%	

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[0098] The Examples show that compositions of the present invention provide a soft, white product that avoids clumping and is thus palatable to use and easy to pack and manufacture. It also has a substantial shelf life and delivers nicotine quickly and consistently to the user.

[0099] Embodiments of the present invention are described in the following numbered paragraphs:

1.A composition comprising:

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- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

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2. A composition according to paragraph 1, further comprising additional ingredients, preferably in an amount from about 1 wt% to about 10 wt% or more preferably in an amount from about 1 wt% to about 8 wt%.

3. A composition according to paragraph 1 or paragraph 2 wherein the additional ingredients comprise one or more additives selected from flavourings, flavour enhancers, sweeteners and preservatives.

4. A composition according to paragraphs 2 or 3 wherein the additional ingredients comprise sweeteners, preferably in an amount from about 1wt% to about 3 wt %.

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5. A composition according to paragraph 4, wherein the sweeteners comprise compounds selected from sugars (such as sucrose, fructose, glucose, dextrose, maltose, lactose, galactose), sugar alcohols (such as xylitol, maltitol, sorbitol, erythritol) and/or sugar substitutes (such as aspartame, saccharin, sucralose, allulose, acesulfame K, cyclamate or steviol glycosides).

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6. A composition according to paragraph 4 or paragraph 5 comprising a sugar alcohol in an amount less than 3 wt%, preferably less than 2 wt%, such as between 1 wt% and 2 wt%.

7. A composition according to any of paragraphs 4 to 6 comprising a sugar substitute in an amount less than 1 wt%, preferably less than 0.5 wt%, such as between 0.05 wt% and 0.3 wt%.

8. A composition according to paragraph 6 or paragraph 7 wherein the or a sugar alcohol comprises xylitol and/or the or a sugar substitute comprises acesulfame K.

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9. A composition according to any of paragraphs 2 to 8 further comprising one or more preservatives selected from calcium chloride, salts of sorbic acid (such as potassium sorbate), salts of benzoic acid (such as sodium benzoate), nitrate salts, nitrite salts, sulfate salts, sulfite salts and propionate salts.

10. A composition according to paragraph 9, wherein potassium sorbate is present in an amount less than about

1wt%, preferably between 0.1wt% and 0.5wt%, such as between about 0.25wt% and about 0.35wt%.

11. A composition according to any of paragraphs 1 to 9, wherein the pH control salts comprise buffering salts such as a combination of ammonium chloride and sodium bicarbonate.

12. A composition according to paragraph 11, where ammonium chloride is present in an amount between 0.05 wt% and 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.15 wt% and 0.25 wt%.

13. A composition according to any preceding paragraph, where sodium bicarbonate is present in an amount between less than 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.2 wt% and 0.3 wt%.

14. A composition according to any preceding paragraph comprising greater than 40wt% water, for example between 40 wt% and 50 wt% water, preferably between about 44 wt% and about 48 wt% water.

15. A composition according to any preceding paragraph wherein the filler material comprises powdered cellulose and/or microcrystalline cellulose (MCC).

16. A composition according to any preceding paragraph, wherein the release control agent comprises agar agar in an amount less than about 1wt%, preferably less than 0.7wt%.

17. A composition according to paragraph 16, wherein the release control agent comprises agar agar in an amount from about 0.2 wt% to about 0.7wt%, preferably in an amount from about 0.2wt% to about 0.5wt%.

18. A composition according to any preceding paragraph, wherein the ratio of agar agar to nicotine is less than about 1.3:1.

19. A composition according to any preceding paragraph, wherein the ratio of agar agar to nicotine is from about 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1.

20. A composition according to any preceding paragraphs further comprising tobacco leaf in an amount less than 5 wt%, preferably about 1 wt% to 3 wt%.

21. A composition according to any preceding paragraph where the pH as measured by Coresta Method No.69, 2017, is from 6 to 9, preferably from 7 to 9 and more preferably from 7 to 8.5.

22. A composition according to any of paragraphs 3 to 21 wherein the flavour enhancers are selected from the group comprising sodium chloride, glutamate salts, glycine salts, inosinic acid salts and 5'-ribonucleotide salts.

23. A composition according to paragraph 22 comprising sodium chloride in an amount less than 8 wt%, preferably between 1 wt% and 7 wt%.

24. A composition according to any of paragraphs 3 to 23 comprising flavouring compounds in an amount less than about 5 wt% of the total composition, for example less than 3 wt% of the composition or between 0.5 wt% and 3 wt% of the composition.

25. A composition according to any preceding paragraph, wherein the the quantity of nicotine is between 0.2wt% and 3 wt%, or between 0.2wt% and 2wt%.

26. A composition according to any preceding paragraph consisting essentially of the described components.

27. A water or saliva permeable pouch containing a composition according to any preceding paragraph.

28. A package containing a plurality of pouches according to paragraph 27.

29. A process for forming a nicotine containing composition according to any of paragraphs 1 to 26 comprising:

a. combining in a mixer native cellulose material in an amount 40 wt% to 60 wt% of the intended composition with agar agar (and/or derivatives of agar agar) powder in an amount 0.2 wt% to 2 wt% of the intended composition, thereby to form a precursor composition;

b. adding water to the precursor composition and mixing at a temperature greater than 50°C;

c. adding to the precursor composition nicotine in free base form, in an amount 0.2wt% to about 2wt% of the intended final composition, while the temperature is greater than 50°C;

d. allowing the mixture to cool.

30. A process according to paragraph 29, wherein additional water is added between steps (c) and (d).

31. A process according to paragraph 29 or 30, wherein in steps (b) and (c), the mixing of the precursor is at a temperature greater than about 60°C, preferably above about 70°C, preferably above 80°C.

32. A process according to any of paragraphs 29 to 31, wherein in step (b) the water is provided to the precursor at a temperature above about 70°C, preferably above about 80°C.

33. A process according to paragraph 32, wherein in step (b) the water is provided to the precursor is in the form of steam or vapour.

34. A process according to any of paragraphs 30 to 33, wherein additional water added between steps (c) and (d) is at a temperature greater than about 70°C, preferably above about 80°C.

35. A process according to any of paragraphs 34, wherein additional water added between steps (c) and (d) is in the form of steam or vapour.

36. A process according to any of paragraphs 29 to 35, wherein the precursor mixture is heated while in the mixer, for example during step (b) and/or (c) and or during or after any addition of water following step (c).

37. A process according to any of paragraphs 29 to 36, wherein further water is added to the composition after step (d).
 38. A process according to any of paragraphs 29 to 37, wherein any of the following components are added to the precursor mixture prior to step (b):

- a. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt% of the intended composition;
- b. additional ingredients, preferably in an amount up to about 12 wt% of the intended composition.

39. A process according to any of paragraphs 29 to 38 where the intended composition is a composition according to any of paragraph 1 to 26.

40. Use as a nicotine release control agent of agar agar in a composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

41. Use as a nicotine stabilising agent of agar agar in a composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

42. A use according to paragraph 38 or paragraph 39, wherein the composition further comprises additional ingredients, preferably in an amount from about 1 wt% to about 10 wt% or more preferably in an amount from about 1 wt% to about 8 wt%.

43. A use according to paragraphs 40 to 42 wherein the additional ingredients in the composition comprise one or more additives selected from flavourings, flavour enhancers, sweeteners and preservatives.

44. A use according to paragraphs 42 or 43 wherein the additional ingredients comprise sweeteners, preferably in an amount from about 1wt% to about 3 wt %.

45. A use according to paragraph 44, wherein the sweeteners comprise compounds selected from sugars (such as sucrose, fructose, glucose, dextrose, maltose, lactose, galactose), sugar alcohols (such as xylitol, maltitol, sorbitol, erythritol) and/or sugar substitutes (such as aspartame, saccharin, sucralose, allulose, acesulfame K, cyclamate or steviol glycosides).

46. A use according to paragraph 44 or paragraph 45 comprising a sugar alcohol in an amount less than 3 wt%, preferably less than 2 wt%, such as between 1 wt% and 2 wt%.

47. A composition according to any of paragraphs 46 comprising a sugar substitute in an amount less than 1 wt%, preferably less than 0.5 wt%, such as between 0.05 wt% and 0.3 wt%.

48. A according to paragraph 46 or paragraph 47 wherein the or a sugar alcohol comprises xylitol and/or the or a sugar substitute comprises acesulfame K.

49. A use according to any of paragraphs 42 to 48 further comprising one or more preservatives selected from calcium chloride, salts of sorbic acid (such as potassium sorbate), salts of benzoic acid (such as sodium benzoate), nitrate salts, nitrite salts, sulfate salts, sulfite salts and propionate salts.

50. A use according to paragraph 49, wherein potassium sorbate is present in an amount less than about 1wt%, preferably between 0.1wt% and 0.5wt%, such as between about 0.25wt% and about 0.35wt%.

51. A use according to any of paragraphs 40 to 49, wherein the pH control salts comprise buffering salts such as a combination of ammonium chloride and sodium bicarbonate.

52. A use according to paragraph 51, where ammonium chloride is present in an amount between 0.05 wt% and 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.15 wt% and 0.25 wt%.

53. A use according to any of paragraphs 40 to 52, where sodium bicarbonate is present in an amount between less than 1wt%, preferably between 0.1wt% and 0.5 wt%, for example between 0.2 wt% and 0.3 wt%.

54. A use according to any of paragraphs 40 to 53, comprising greater than 40wt% water, for example between 40 wt%

and 50 wt% water, preferably between about 44 wt% and about 48 wt% water.

55. A use according to any of paragraphs 40 to 54 wherein the filler material comprises powdered cellulose and/or microcrystalline cellulose (MCC).

56. A use according to any of paragraphs 40 to 55, wherein the release control agent comprises agar agar in an amount less than about 1wt%, preferably less than 0.7wt%.

57. A use according to paragraph 56, wherein the release control agent comprises agar agar in an amount from about 0.2 wt% to about 0.7wt%, preferably in an amount from about 0.2wt% to about 0.5wt%.

58. A use according to any of paragraphs 40 to 57, wherein the ratio of agar agar to nicotine is less than about 1.3:1.

59. A use according to any of paragraphs 40 to 58, wherein the ratio of agar agar to nicotine is from about 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1.

60. A use according to any of paragraphs 40 to 59 further comprising tobacco leaf in an amount less than 5 wt%, preferably about 1 wt% to 3 wt%.

61. A use according to any of paragraphs 40 to 60 where the pH as measured by Coresta Method No.69, 2017, is from 6 to 9, preferably from 7 to 9 and more preferably from 7 to 8.5.

62. A use according to any of paragraphs 43 to 61 wherein the flavour enhancers are selected from the group comprising sodium chloride, glutamate salts, glycine salts, inosinic acid salts and 5'-ribonucleotide salts.

63. A use according to paragraph 62 comprising sodium chloride in an amount less than 8 wt%, preferably between 1 wt% and 7 wt%.

64. A use according to any of paragraphs 43 to 63 comprising flavouring compounds in an amount less than about 5 wt% of the total composition, for example less than 3 wt% of the composition or between 0.5 wt% and 3 wt% of the composition.

65. A use according to any of paragraphs 40 to 64, wherein the quantity of nicotine is between 0.2wt% and 3 wt%, or between 0.2wt% and 2wt%

66. A use according to any of paragraphs 40 to 65, wherein the composition consists essentially of the described components.

[0100] The invention is described in the following claims:

Claims

1. A composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

2. A composition according to claim 1, wherein the ratio of agar agar to nicotine is from about 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1.

3. A water or saliva permeable pouch containing a composition according to claims 1 or 2.

4. A package containing a plurality of pouches according to claim 3.

5. A process for forming a nicotine containing composition according to claims 1 or 2 comprising:

- a. combining in a mixer native cellulose material in an amount 40 wt% to 60 wt% of the intended composition with agar agar (and/or derivatives of agar agar) powder in an amount 0.2 wt% to 2 wt% of the intended composition, thereby to form a precursor composition;
- b. adding water to the precursor composition and mixing at a temperature greater than 50°C;
- c. adding to the precursor composition nicotine in free base form, in an amount 0.2wt% to about 2wt% of the intended final composition, while the temperature is greater than 50°C;
- d. allowing the mixture to cool.

6. A process according to claim 5 where the intended composition is a composition according to claims 1 or 2.

7. Use of agar agar as a nicotine stabilising agent in a composition comprising:

- a. From about 0.2wt% to about 5wt% nicotine in free base form;
- b. a native cellulose material in an amount from about 35 wt% to about 60 wt%;
- c. water in an amount at least 35 wt%;
- d. one or more pH control salts in an amount from about 0.5 wt% to about 3 wt%;
- e. a release control agent comprising agar agar and/or derivatives of agar agar in an amount from about 0.1wt% to about 2 wt%;
- f. optional additional ingredients, preferably in an amount up to about 12 wt%.

8. A use according to claim 7 comprising a sugar alcohol in an amount less than 3 wt%, preferably less than 2 wt%, such as between 1 wt% and 2 wt%.

9. A use according to claims 7 or 8, comprising greater than 40wt% water, for example between 40 wt% and 50 wt% water, preferably between about 44 wt% and about 48 wt% water.

10. A use according to any of claims 7 to 9 wherein the native cellulose material comprises powdered cellulose and/or microcrystalline cellulose (MCC).

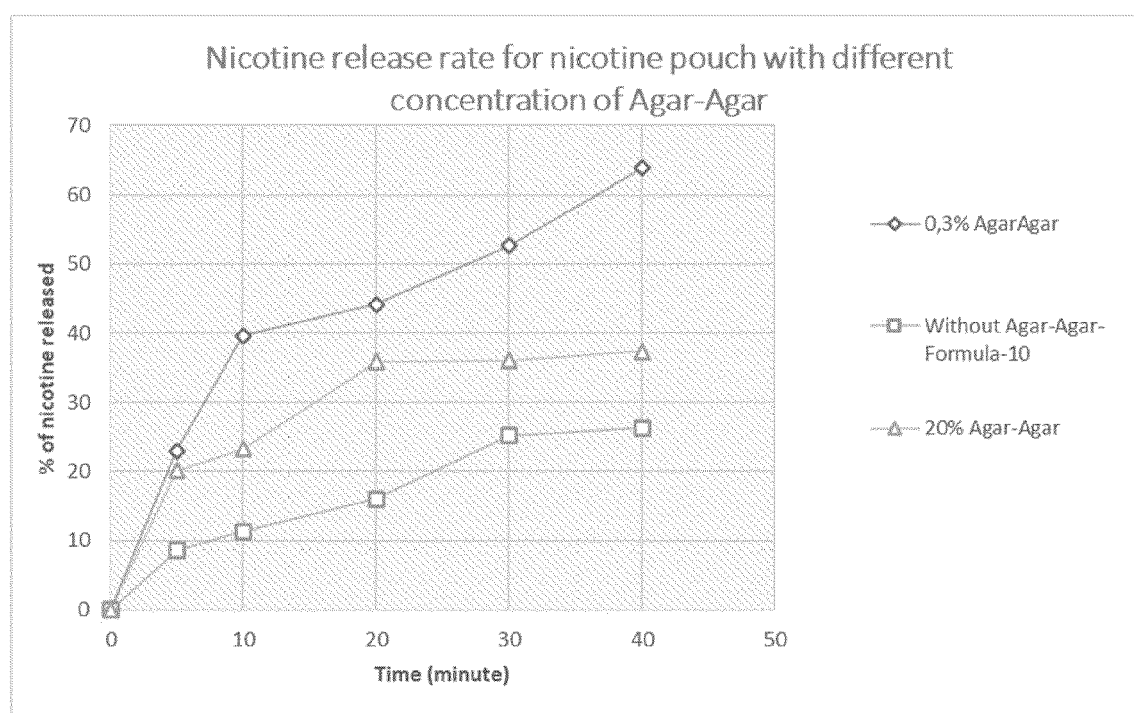
11. A use according to any of claims 7 to 10, wherein the release control agent comprises agar agar in an amount less than about 1wt%, preferably less than 0.7wt%.

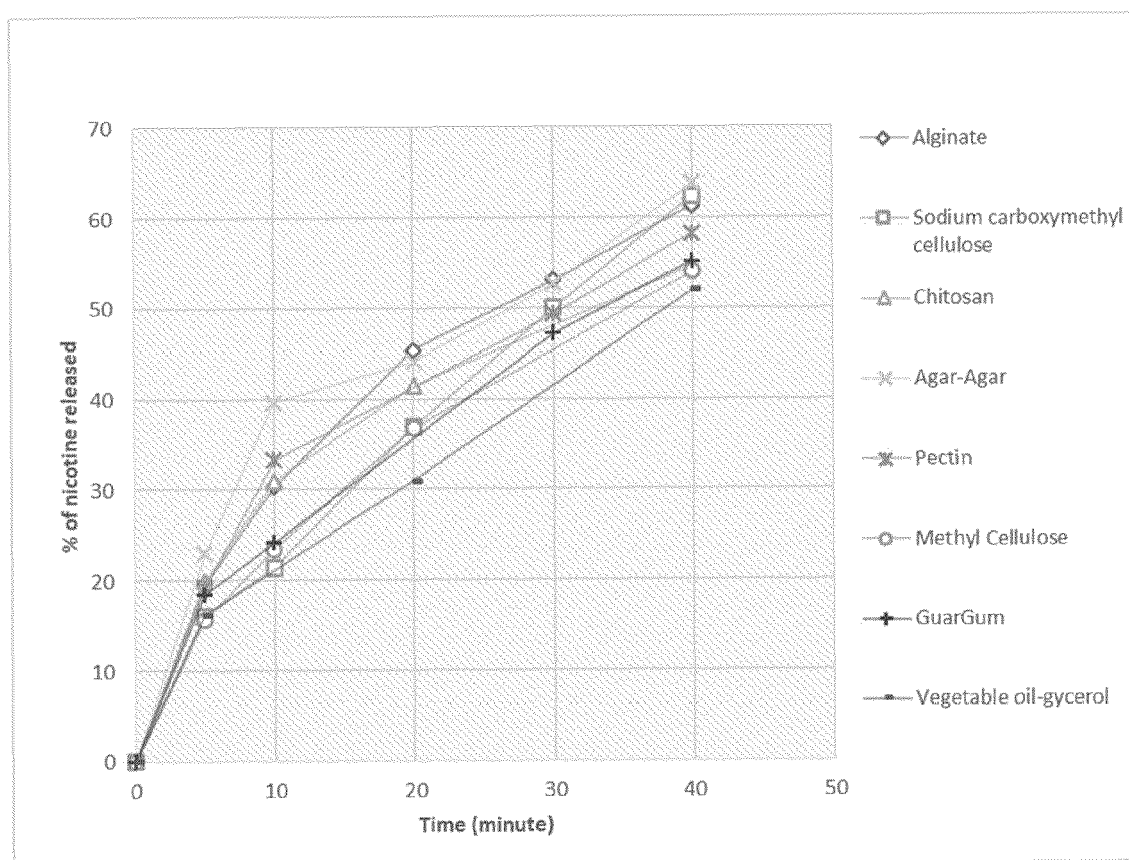
12. A use according to claim 11, wherein the release control agent comprises agar agar in an amount from about 0.2 wt% to about 0.7wt%, preferably in an amount from about 0.2wt% to about 0.5wt%.

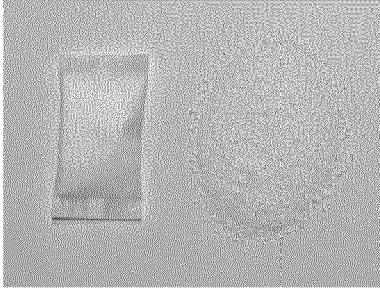
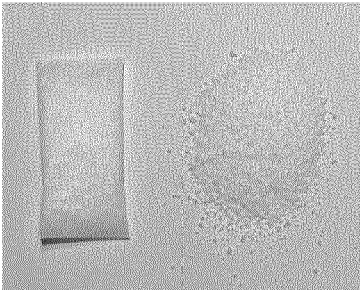
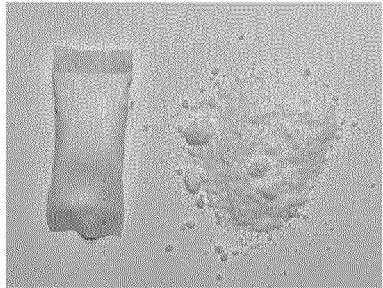
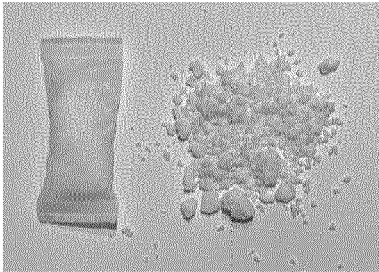
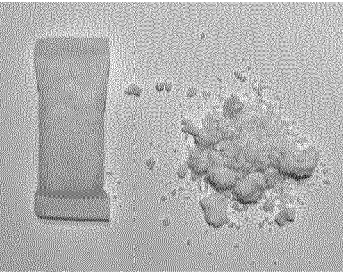
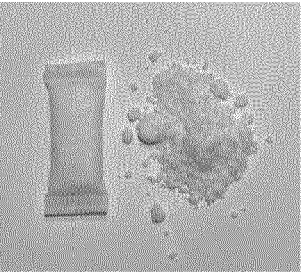
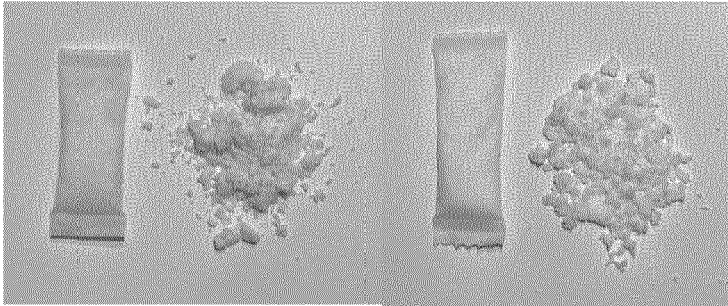
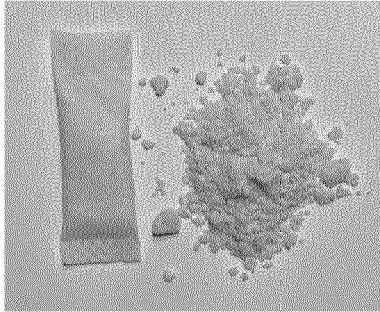
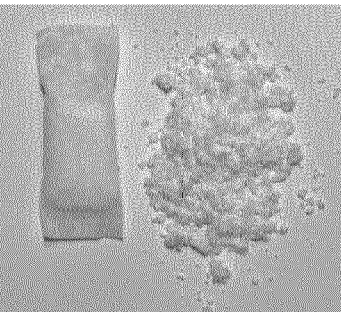
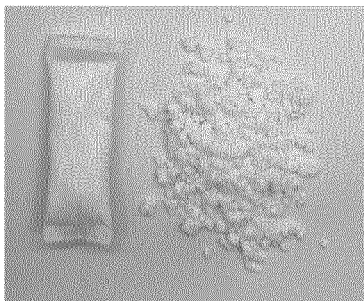
13. A use according to any of claims 7 to 12, wherein the ratio of agar agar to nicotine is less than about 1.3:1.

14. A use according to any of claims 7 to 13, wherein the ratio of agar agar to nicotine is from about 0.1:1 to about 1.2:1, preferably from about 0.1:1 to about 1:1, more preferably from about 0.1:1 to about 0.8:1.

15. A use according to any one of claims 7 to 14, wherein the quantity of nicotine is between 0.2wt% and 3 wt%, or between 0.2wt% and 2wt%.





Comparative Example 10	Comparative Example 11	Comparative Example 12
		
Comparative Example 13	Comparative Example 14	Comparative Example 15
		
Comparative Example 16	Comparative Example 17	
		
Comparative Example 18	Comparative Example 19	Example 2
		

REFERENCES CITED IN THE DESCRIPTION

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