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(54) A FLAVOURED MOIST ORAL POUCHED NICOTINE PRODUCT COMPRISING ETHYL CELLULOSE

(57) There is disclosed an oral pouched nicotine product comprising a moist filling material and a saliva-permeable pouch of a packaging material enclosing the moist filling material, the moist filling material comprising:
- a non-tobacco material;
- a non-encapsulated flavouring agent;
- a nicotine source;
- a pH adjusting agent;
- ethyl cellulose; and
- optionally a tobacco material in an amount within the range of from 0.1 % to 10% by weight, based on the total weight of the moist filling material.

There is also provided a method for manufacture of the oral pouched nicotine product, as well as use of ethyl cellulose for flavour preservation and/or improved shelf life stability in an oral pouched nicotine product.

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Description

TECHNICAL FIELD

[0001] The present disclosure relates to an oral pouched nicotine product comprising a moist filling material including a non-tobacco material, such as microcrystalline cellulose and/or non-tobacco fibres, a non-encapsulated flavouring agent, a nicotine source, a pH adjusting agent and ethyl cellulose. The oral pouched nicotine product may be free from tobacco or contain a small amount of tobacco.

BACKGROUND

[0002] Moist snuff for oral use is available in loose form or portion-packed in a saliva-permeable, porous wrapper material forming a pouch. Pouched moist snuff may be used by the user by placing the pouch between the upper or lower gum and the lip or cheek and retaining it there for a limited period of time. The pouch material holds the tobacco in place while allowing saliva to pass into the interior of the pouched product and allowing flavours and nicotine to diffuse from the tobacco material into the user's mouth.

[0003] There are also tobacco-free or substantially tobacco-free oral pouched nicotine-containing products available which may be offered as alternatives to oral pouched smokeless tobacco products. These tobacco-free or substantially tobacco-free oral pouched non-tobacco nicotine-containing products are generally used in the same manner as the oral pouched tobacco-containing products and are herein referred to as oral pouched nicotine products.

[0004] Oral pouched smokeless tobacco products as well as oral pouched nicotine products may be produced by measuring portions of the filling material and inserting the portions into a packaging material. The packaging material forming the pouch in oral pouched products may be a dry-laid bonded nonwoven comprising viscose rayon fibres (i.e. regenerated cellulose) and an acrylic polymer that acts as binder in the nonwoven material and provides for heat-sealing of the pouches during manufacturing thereof. The packaging material forming the pouch of the oral pouched product should during manufacturing of the pouch provide for sealing, upon storage of the pouch exhibit none or a low degree of discoloration and upon usage by a consumer preserve integrity and strength, allow for a desired release profile of nicotine and flavours and provide a pleasant mouth-feel.

[0005] WO 2004/056363 A2 discloses a nicotine-containing particulate material comprising a combination of nicotine or a pharmaceutically acceptable salt, complex or solvate thereof and a microcrystalline cellulose.

[0006] WO 2007/104573 A2 discloses the use of a nicotine-cellulose combination for the preparation of a snuff composition. The nicotine-cellulose combination may be enclosed in a membrane material.

[0007] WO 2010/114445 A1 discloses a plant fiber product for oral use containing a mixture of plant fibers, such as tea, coffee, tobacco, cocoa, maize, herbs, yerba mate or cellulose, and an alginate composition dispersed in the product and comprising water, alginate and an added substance intended to be released from the product when said product is used. The added substance may be an active substance, such as nicotine, or a taste substance.

[0008] WO 2012/134380 A1 discloses a product for oral delivery of nicotine containing a core comprising a powder of at least one free nicotine salt, at least one pH adjusting agent and at least one filler, and a water insoluble pouch enclosing the powder.

[0009] US9801409 B1 discloses a moist snuff composition comprising grape tissue and a humectant, wherein the grape tissue comprises ground grape skins, ground grape pulp and/or ground grape seeds. The composition may further comprise an additive such as an abrasive, an antioxidant, an acidity regulator, an anti-caking agent, an emulsifier, a flavourant, a glazing agent, a herbal supplement, a mineral supplement, a stimulant, a thickening, stabilizer and/or gelling agent, and/or a vitamin agent.

[0010] The organoleptic properties, such as texture, aroma, taste, shape and appearance, of the pouched product are of high importance to the user. It is generally desirable to provide oral pouched nicotine products with rapid release of flavour and nicotine to provide an initial strong flavour experience and/or reduce nicotine craving. However, a significant amount of flavour added to the product may be lost or changed by e.g. deterioration before the product is used due to, for instance, exposure to moisture, oxidation, and evaporation of the flavour(s). A further problem associated with the incorporation of flavour(s) in pouched nicotine product is that the flavour(s) may not be retained in the filling material when the product is stored. As a result, a consumer may not enjoy the flavour as intended. Generally, this problem is greater for moist oral pouched nicotine products than for dry oral pouched nicotine products.

[0011] Another problem associated with the incorporation of flavours in pouched nicotine products is that some flavours may have negative impact on the seal strength of the resulting pouches which may lead to seal rupture upon storage of the products. In particular, impaired seal strength upon storage is a problem for moist oral pouched products.

[0012] The above-mentioned problems associated with flavour preservation and impaired seal strength have been addressed by incorporation of triglyceride and monoglyceride, respectively, in oral pouched nicotine products.

[0013] WO 2018/197454 A1 discloses an oral pouched nicotine product comprising triglyceride. Less flavour lost

during storage, improved seal strength upon storage as well as improved shelf life were found in the oral moist pouched product comprising triglyceride in comparison to an oral pouched nicotine product comprising a moist filling material without triglyceride.

[0014] WO 2019/115778 A1 discloses an oral pouched nicotine product comprising monoglyceride for flavour preservation, prevention of pouch seal weakening and/or improved shelf life.

[0015] However, while triglyceride and monoglyceride have been found to satisfactorily alleviate at least one of the problems mentioned above some consumers may be concerned by their presence for e.g. dietary, religious and/or ethical reasons. For instance, vegetarians and people with religious dietary restrictions may want to ascertain that the triglycerides and monoglycerides do not originate from animal fat such as pork or beef, and patients on fat-restricted diets may want to limit fat intake. Further, monoglycerides and triglycerides may require pre-treatment such as melting prior to being incorporated into the oral pouched nicotine product thereby adding an extra process step.

[0016] Thus, there is a need for flavoured oral pouched nicotine products comprising no tobacco or a small amount of tobacco allowing the consumer to enjoy the flavour as intended. In particular there is a need for such flavoured oral pouched nicotine products which is versatile with respect to the consumer's needs and preferences as well as minimize the risk for intolerancies and sensitivities. Further, there is a need for flavoured oral pouched nicotine products which may be easily manufactured.

SUMMARY

[0017] An object of the present disclosure is to alleviate at least one of the problems discussed above, and/or to provide advantages and aspects not provided by hitherto known technique.

[0018] The present disclosure provides an oral pouched nicotine product comprising a moist filling material and a saliva-permeable pouch of a packaging material enclosing the moist filling material, the filing material comprising:

- a non-tobacco material, such as a particulate and/or fibrous non-tobacco material;
- a non-encapsulated flavouring agent;
- a nicotine source;
- a pH adjusting agent;
- ethyl cellulose, and
- optionally a tobacco material in an amount within the range of from 0.1% to 10% by weight, based on the total weight of the moist filling material.

[0019] The present disclosure also provides a use of ethyl cellulose for flavour preservation, prevention of pouch seal weakening and/or improved shelf life stability in an oral pouched nicotine product such as an oral pouched non-tobacco nicotine product, an oral pouched low tobacco product and/or an oral pouched nicotine product as described herein.

[0020] There is also provided a method for manufacturing a moist filling material as disclosed herein, the method comprising:

- providing a mixture comprising a non-tobacco material, such as a particulate non-tobacco material and/or a fibrous non-tobacco material and a nicotine source,

- adding water to the mixture comprising non-tobacco material and nicotine source,

wherein ethyl cellulose, a non-encapsulated flavouring agent, a pH adjusting agent and optionally a tobacco material are added independently in and/or after any of the foregoing steps.

[0021] There is also provided a method for manufacturing an oral pouched nicotine product as described herein, the method comprising the steps of:

a) providing a moist filling material as described herein or produced as described herein, and
b) enclosing the moist filling material from step a) in a saliva-permeable pouch thereby providing an oral pouched nicotine product.

DEFINITIONS

[0022] The term "tobacco material" is used herein for fibrous material of tobacco leaves or parts of leaves, such as lamina and stem. The leaves and parts of leaves may be finely divided (disintegrated), such as ground, cut, shredded or threshed, and the parts of leaves may be blended in defined proportions in the tobacco material. The tobacco material may comprise or be free from tobacco extract.

[0023] By "tobacco" as used herein is meant any part, e.g., 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.

[0024] "Oral" and "oral use" is in all contexts used herein as a description for use in the oral cavity of a human, such as buccal placement.

[0025] As used herein, the term "moisture content" refers to the total amount of oven volatile ingredients, such as water and other oven volatiles (e.g. propylene glycol) in the preparation, composition or product referred to. The moisture content is given herein as percent by weight (wt%) of the total weight of the preparation, composition or product referred to.

[0026] The moisture content as referred to herein may be determined by using a method based on literature references Federal Register/ vol.74, no. 4/712-719/Wednesday, January 7, 2009/Notices "Total moisture determination" and AOAC (Association of Official Analytical Chemics), Official Methods of Analysis 966.02: "Moisture in Tobacco" (1990), Fifth Edition, K. Helrich (ed). In this method, the moisture content is determined gravimetrically by taking 2.5±0.25 g sample and weighing the sample at ambient conditions, herein defined as being at a temperature of 22°C and a relative humidity of 60%, before evaporation of moisture and after completion of dehydration. Mettler Toledo's Moisture Analyzer HB43, a balance with halogen heating technology, is used (instead of an oven and a balance as in the mentioned literature references) in the experiments described herein. The sample is heated to 105°C (instead of 99.5±0.5°C as in the mentioned literature references). The measurement is stopped when the weight change is less than 1 mg during a 90 seconds time frame. The moisture content as weight percent of the sample is then calculated automatically by the Moisture Analyzer HB43.

[0027] In this document, the expressions "per cent by weight", weight% and wt% are used interchangeably.

[0028] Some fibrous materials may exhibit hygroscopic properties. Hygroscopic materials maintain equilibrium moisture content depending on the ambient moisture and temperature.

[0029] "Flavour" or "flavouring agent" is used herein for a substance used to influence the aroma and/or taste of the nicotine product, including, but not limited to, essential oils, single flavour compounds, compounded flavourings, and extracts.

[0030] As used herein "% w/w" or "wt%" or "weight %" or "% by weight" refers to the weight percent of the ingredient referred to of the total weight of the preparation, composition or product referred to.

[0031] As used herein, reference to "dry weight percent", "% by weight, based on dry weight" and the like refers to the weight percent of the ingredient referred to on the basis of the total weight of the dry ingredients, i.e. all ingredients of the preparation, composition or product referred to excluding the moisture content.

[0032] As used herein, reference to "wet weight percent", "% by weight, based on wet weight" and the like refers to the weight percent of the ingredient referred to on the basis of the total weight of the ingredients, i.e. all ingredients of the preparation, composition or product referred to including the moisture content. Thus, "% by weight, based on total weight" as used herein is the same as "% by weight, based on wet weight".

[0033] As used herein the terms "pouched nicotine product for oral use" or "oral pouched nicotine product" refer to a portion of nicotine-containing filling material packed in a saliva-permeable pouch material intended for oral use.

[0034] As used herein the terms "oral pouched nicotine non-tobacco product", "oral pouched nicotine product free from tobacco" or "oral pouched tobacco-free product" refer to a portion of nicotine-containing filling material packed in a saliva-permeable pouch material intended for oral use wherein no tobacco is included in said product.

[0035] As used herein the term "oral pouched nicotine tobacco product" or "low tobacco oral pouched nicotine product" refers to a portion of nicotine-containing filling material packed in a saliva-permeable pouch material intended for oral use wherein an amount of tobacco material within the range of from about 0.1 % to about 10% by weight or from about 0.1% to about 5% by weight, based on the total weight of the filling material, is included in said product.

[0036] As used herein, the term "ethyl cellulose" refers to a derivative of cellulose in which some of the hydroxyl groups have been converted to ethyl ether groups. While complete replacement of the hydroxyl groups with ethoxy groups is possible yielding triethyl cellulose, usually 2 to 2.5 ethoxy groups are present on the repeating glucose units. This is called the degree of substitution. Triethyl cellulose thus has a degree of substitution equal to three.

[0037] As used herein, the term "particulate" refers to a component in the form of particles, including granules, pellets, powder, etc.

[0038] As used herein, the term "fibrous" refers to a component which is constituted by natural or man-made fibers or which is substantially constituted by natural or man-made fibers.

[0039] As used herein, the term "non-particulate" refers to a component which is not in the form of particle(s).

DESCRIPTION

[0040] The present disclosure provides an oral pouched nicotine product comprising a moist filling material and a saliva-permeable pouch of a packaging material enclosing the moist filling material, the moist filling material comprising:

- a non-tobacco material such as a particulate and/or a fibrous non-tobacco material,
- a non-encapsulated flavouring agent,
- a nicotine source,
- a pH adjusting agent,
- ethyl cellulose; and
- optionally a tobacco material within the range of from about 0.1% to about 10% by weight, based on the total weight of the moist filling material.

[0041] The oral pouched nicotine product may be free from tobacco, i.e. it does not contain tobacco, thereby providing an oral pouched nicotine tobacco-free product. Alternatively, the oral pouched nicotine product may comprise a small amount of tobacco material, such as from about 0.1% by weight to about 10% by weight based on the total weight of the moist filling material, thereby providing a low tobacco oral pouched nicotine product. For example, the low tobacco oral pouched nicotine product may comprise a moist filling material comprising from 0.1% by weight to about 10% by weight, such as from about 0.1% by weight to about 5% by weight such as from about 0.2% by weight to about 1% by weight of tobacco material based on the total weight of the moist filling material. In particular, the low tobacco oral pouched nicotine product may comprise a moist filling material comprising from about 0.2% by weight to about 1% by weight of tobacco material based on the total weight of the moist filling material. It will be appreciated that the tobacco material in the low tobacco oral nicotine product described herein forms part of the moist filling material.

[0042] The tobacco material may be a purified tobacco material, such as a bleached tobacco material. Further, the tobacco material described herein may comprise one, two or more non-tobacco materials, such as two or more particulate non-tobacco materials, two or more fibrous non-tobacco materials or mixtures of one or more particulate non-tobacco material and one or more fibrous non-tobacco material. The tobacco material may be provided as tobacco fibers, ground tobacco and/or as snuff such as snus.

[0043] The moist filling material of the oral pouched nicotine product described herein may have a moisture content within the range of from about 10% to about 60% by weight, such as from about 40% to about 60% by weight, such as from about 35% to about 55% by weight, such as about 35% to about 45% by weight, such as about 30% to about 40% by weight, such as from about 50% to about 60% by weight, based on the total weight of the moist filling material. For example, the moisture content may be within the range of from about 5 % by weight to about 30 % by weight, based on the total weight of the moist filling material. In a further example, the moisture content may be from about 35 % by weight to about 55% by weight, such as from about 35% to 50% by weight, based on the total weight of the filling material.

[0044] Unless otherwise stated, the moisture content of the moist filling material described herein equals or substantially equals the moisture content of the oral pouched nicotine product described herein.

[0045] Importantly, the moist filling material described herein comprises ethyl cellulose. It has unexpectedly been found that ethyl cellulose reduces migration of flavour from the moist filling material of the oral pouched nicotine product to the pouch wrapper material. As a result, the consumer may enjoy the flavoured product as intended. Surprisingly, it has also been found that the presence of ethyl cellulose improves pouch seal strength. The risk for pouch seal rupture is therefore reduced.

[0046] The ethyl cellulose may be provided in a form that is easy to handle and/or use. For instance, the ethyl cellulose may be provided as a powder or as a solution. For example, the ethyl cellulose may be provided as a dry free-flowing powder or as a solution comprising an alcohol such as ethanol. Further, pre-treatment such as melting prior to use of the ethyl cellulose may not be required, which facilitates use and/or handling thereof. Thus, the use of ethyl cellulose increases the versatility such as versatility in the manufacturing process of the oral pouched nicotine product.

[0047] The hydroxyl groups of the ethyl cellulose may be substituted with ethoxyl groups to a varying degree. A high degree of substitution corresponds to a high content of ethoxyl groups in the ethyl cellulose. For example, ethyl cellulose with a degree of substitution of 3 corresponds to about 55% ethoxyl content. In a further example, a degree of substitution from about 2.15 to about 2.6 corresponds to an ethoxyl content from about 43 % to about 50%. The degree of substitution will affect the characteristics of the ethyl cellulose such as its solvent solubility. For instance, ethyl cellulose that contains no less than about 46.5% of ethoxyl groups is soluble in solvents such as chloroform, ethanol, ethyl acetate, methanol and toluene. While not wishing to be bound by any specific theory, it is believed that the ethyl cellulose may be selected to have characteristics suiting a particular flavouring agent so that the flavouring agent is retained in the moist filling material of the oral pouched nicotine product. For instance, a flavouring agent that is moist soluble in ethanol may be combined with ethanol soluble ethyl cellulose such as ethyl cellulose containing no less than about 46.5% of ethoxyl groups. Since flavouring agents differ in characteristics such as solvent solubility, lipohilicity, hydrophilicity etc. the ethyl cellulose may be selected to match the characteristics of the flavouring agent(s) used.

[0048] The ethyl cellulose described herein may have a degree of substitution from about 0.8 to about 3, such as from about 1 to about 3, such as from about 1.5 to about 3, such as from about 2 to about 3, such as from about 2.5 to about 3. For example, the ethyl cellulose described herein may have a degree of substitution from about 2 to about 3 and/or about an ethoxyl content from about 45% to about 55% such as from about 48% to about 49.5%.

[0049] The ethyl cellulose may be present in the moist filling material in an amount from about 0.1% to about 10% by weight, such as from about 0,1% to about 8% by weight, such as from about 0.1% to about 6% by weight, such as from about 0.1% to about 5% by weight, such as from about 0,1% to about 3% by weight, such as from about 0,5% to about 10% by weight, such as from about 0,5% to about 8% by weight, such as from about 0.5% to about 5% by weight, such as from about 0.5% to about 3% by weight, such as from 1% to about 4%, or such as from about 1% to about 3% by weight, such as 0.3% to 3% by weight, based on the total weight of the moist filling material. For instance, the ethyl cellulose may be present in an amount of about 1%, about 2% or about 3% based on the total weight of the moist filling material. In an example, the ethyl cellulose may be present in an amount of about 1 % based on the total weight of the moist filling material.

[0050] The moist filling material may comprise within the range of from about 30% to about 80% by weight of the non-tobacco material, based on total weight of the moist filling material.

[0051] The non-tobacco material may be water insoluble. Further, the non-tobacco material may comprise cellulose such as cellulose selected from the group consisting of microcrystalline cellulose and cellulose. A particulate non-tobacco material may comprise a combination of cellulose, such as microcrystalline cellulose and/or powdered cellulose, and one or more water-insoluble fibers as described herein. In particular, a particulate non-tobacco material may comprise or consist of microcrystalline cellulose such as a powder of microcrystalline cellulose. Further, a particulate non-tobacco material may comprise starch and/or silicon.

[0052] The moist filling material may comprise one, two or more non-encapsulated flavouring agents. As used herein, an encapsulated flavouring agent is a flavouring agent contained within a capsule. Accordingly, a non-encapsulated flavouring agent is not contained within a capsule. The flavouring agent described herein may be a non-encapsulated non-particulate flavouring agent. For instance, the flavouring agent of the moist filling material in the oral pouched nicotine product as disclosed herein may be a synthetic flavour, a plant based flavour, a flavour oil, a hydrophobic flavour oil such as an essential oil, such as a nature-identical flavour. As used herein, a nature-identical flavour intends a synthetic flavour which is chemically identical to natural flavourings but are prepared or extracted using chemical methods. The flavouring agent may be a mixture of different flavours. The flavouring agent may be provided as oil such as a hydrophobic oil, a liquid, a powder or a mixture thereof. Further, the flavouring agent(s) may be in the form of a liquid and/or a solid. The flavouring agent may be stable at pH > 7.

[0053] Examples of flavours of the flavouring agent(s) include bergamot, eucalyptus, orange, mandarin, citrus, lemon, peppermint, spearmint, mint, menthol, liquorice, wintergreen, whiskey, rum, cherry, various berries, tobacco, coffee, vanilla, lime, apple, peach, carvone, limonene and any combination of two or more thereof.

[0054] The moist filling material of the oral pouched nicotine product as disclosed herein may comprise within the range of from about 0.5% to about 5.0% by weight, such as from 0.5% by weight to about 3 % by weight, of the flavouring agent, based on the total weight of the moist filling material.

[0055] The moist filling material may further comprise an encapsulated flavouring agent. The encapsulated flavouring agent may be the same or different from the non-encapsulated flavouring agent. Alternatively, the moist filling material may be free from encapsulated flavouring agent.

[0056] The moist filling material of the oral pouched nicotine product described herein may be provided as a powder or granulate. In particular, the moist filling material enclosed by the saliva-permeable pouch of the packaging material may be provided in a non-compressed form.

[0057] The moist filling material may comprise the nicotine source in an amount within a range of from about 0.5% to about 10% calculated as nicotine base, based on the total weight of the moist filling material.

[0058] The nicotine source may be selected from the group consisting of nicotine base, nicotine polacrilex, nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate, nicotine salicylate, and any combination(s) thereof. In particular, the moist filling material may comprise or consist of one of more of the following: nicotine bitartrate, nicotine bitartrate dihydrate, an aqueous solution comprising nicotine base and tartaric acid such as an aqueous solution comprising about 20% by weight of nicotine base and about 10% by weight of tartaric acid, based on the total weight of the aqueous solution.

[0059] It will be appreciated that the nicotine source described herein does not comprise tobacco such as tobacco material.

[0060] The amount of nicotine source per pouched product may be within the range from about 0.1 mg to about 30 mg of nicotine calculated as nicotine base, such as about 0.5 mg, about 1.0 mg, about 1.5 mg, about 2.0 mg, about 2.5 mg, about 3.0 mg, about 3.5 mg, about 4.0 mg, about 4.5 mg, about 5.0 mg, about 6.0 mg, about 7.0 mg, about 8.0 mg, about 9.0 mg, about 10 mg, about 11 mg, about 12, about 13 mg, about 14,about 15 mg, about 16 mg, about 17 mg, about 18 mg, about 19 mg, about 20 mg, about 21 mg, about 22 mg, about 23 mg, about 24 mg or about 25 mg of nicotine. As used herein, mg stands for milligram(s).

[0061] The moist filling material described herein may comprise one, two or more pH adjusting agents. The amount of pH adjusting agent may be selected such that the moist filling material when dispersed in purified water provides a pH above 7.0, such as a pH within the range of from about 7.0 to about 10.0 or a pH within the range of from about 8.0

to about 9.0, such as a pH within the range of from about 8.3 to about 8.9. For example, the pH adjusting agent(s) may be present in an amount of from about 1.0% to about 15% by weight, based on total weight of the moist filling material. Examples of pH adjusting agents that may be present in the moist filling material include one or more of the following: Na_2CO_3, K_2CO_3, $NaHCO_3$, $KHCO_3$. For instance, the pH adjuster may be Na_2CO_3 which may be present in an amount within the range of from about 0.3% w/w to about 5% w/w based on the total weight of the moist filling material.

[0062] The pH of the moist filling material may be measured by adding 100 ml of distilled water to 5.0 gram of moist filling material, for instance in a 100 ml Erlenmeyer flask, stirring the resulting mixture at room temperature with a magnetic stirrer at 100 rpm for about 5 minutes, and then measuring the pH of an extract obtained therefrom with a calibrated (according to the manufacturer's instructions) pH meter. For correctness of readings, the sample solutions shall be analyzed within one hour. In this document, the term "rpm" stands for revolutions per minute. Further, in this document the expression "room temperature" stands for from about 20°C to about 25°C such as about 22°C.

[0063] Examples of suitable pH adjusting agents are sodium carbonate, sodium hydroxide, potassium hydroxide, potassium carbonate, sodium carbonate, sodium bicarbonate and magnesium carbonate. These pH adjusting agents may be used alone or in combination of two or more thereof.

[0064] The moist filling material described herein may further comprise water-insoluble non-tobacco fibers selected from the group consisting of maize fibers, oat fibers, tomato fibers, barley fibers, rye fibers, sugar beet fibers, buck wheat fibers, wheat fibers, pea fibers, potato fibers, apple fibers, cocoa fibers, bamboo fibers, citrus fibers, and any combination thereof. The water-insoluble fibers described herein may form part of said non-tobacco material. In particular, the moist filling material described herein may comprise bamboo fibres. In particular, the bamboo fibres may be present in from about 3% by weight to about 50% by weight, such as from about 4% by weight to about 5% by weight, based on the total weight of the product. Alternatively, the moist filling material may be free from water-insoluble non-tobacco fibers such as bamboo fibers.

[0065] It will be appreciated that the moist filling material described herein, in particular any water-insoluble fibers of the moist filling material described herein, may be free from any component or constituent associated with allergies or intolerancies. For instance, the moist filling material and/or the water-insoluble fibers may be free for any component or constituent associated with fruits, such as stone fruits. For example, the moist filling material and/or the water-soluble fibers may be free from grapes such as grape tissue.

[0066] The non-tobacco material, the non-encapsulated flavouring agent, the nicotine source, the pH adjusting agent, the ethyl cellulose and optionally the tobacco material may be homogeneously mixed, i.e. provided as a uniform mixture. Thus, there is provided an oral pouched nicotine product as described herein wherein the moist filling material components are homogenously mixed such as substantially homogenously mixed.

[0067] The moist filling material of the oral pouched nicotine product as disclosed herein may also comprise a salt selected from the group consisting of sodium chloride, potassium chloride, magnesium chloride, calcium chloride and any combination of two or more thereof. For example, the moist filling material of the oral pouched nicotine product as disclosed herein may comprise within the range of from about 1.0% w/w to about 10% w/w, such as from about 2.0% w/w to about 5% w/w, based on the total weight of the moist filling material, of a salt as described herein such as sodium chloride. Additionally or alternatively, the moist filling material may comprise magnesium chloride and/or calcium chloride. Together with the pH adjuster described herein the magnesium chloride and/or calcium chloride may aid in stabilizing the pH in the moist filling material. The magnesium chloride and/or calcium chloride may be present in the moist filling material in an amount within the range of from about 0.1% w/w to about 3.5% w/w based on the total weight of the moist filling material.

[0068] The moist filling material of the oral pouched nicotine product described herein may further comprise a humectant such as glycerol and/or propylene glycol. The humectant may be present in an amount within the range of from about 5% w/w to about 15% w/w, based on the total weight of the moist filling material. In particular, the moist filling material of the oral pouched product may comprise about 10% by weight of glycerol, based on the total weight of the moist filling material.

[0069] The moist filling material of the oral pouched nicotine product described herein may further comprise a sweetener such as a natural or artificial sweetener. The artificial sweetener may comprise acesulfame potassium. The sweetener may be present in an amount within the range of from about 0.05% w/w to about 1% w/w based on the total weight of the moist filling material. The sweetener and the salt may together form a taste enhancer. Alternatively, the moist filling material may lack a sweetener.

[0070] The oral pouched nicotine product described herein may be free from one or more of the following: monoglyceride(s), triglyceride(s), anatabine. When the oral pouched nicotine product comprises tobacco material, the product may not comprise anatabine in addition to the anatabine present in said tobacco material.

[0071] There is also provided a use of ethyl cellulose as described herein for flavour preservation, prevention of pouch seal weakening and/or shelf life stability in an oral pouched nicotine product such as an oral pouched tobacco-free nicotine product and/or such as an oral pouched low tobacco nicotine product described herein. In particular, the flavour preservation and/or shelf life stability may be improved at room temperature, i.e. from about 20°C to about 25°C such

as 22°C, compared to a corresponding product in which ethyl cellulose is lacking. Further, the prevention of pouch seal weakening may be improved if stored in refrigerator, i.e. from about 4°C to about 8°C, compared to a corresponding product in which ethyl cellulose is lacking.

[0072] The moist filling material as disclosed herein may be manufactured using a method comprising:

- providing a mixture comprising a non-tobacco material and a nicotine source
- adding water to the mixture comprising non-tobacco material and nicotine source

wherein ethyl cellulose, a non-encapsulated flavouring agent, a pH adjusting agent and optionally a tobacco material independently are added in and/or after any of the foregoing steps.

[0073] The method may also comprise a step of enclosing the moist filling material in a saliva-permeable pouch of a packaging material thereby providing an oral pouched nicotine product as disclosed herein.

[0074] Thus, there is provided a method for manufacturing an oral pouched nicotine product, the method comprising the steps of:

a) providing a filling material as described herein or produced as described herein, and
b) enclosing the filling material from step a) in a saliva-permeable pouch thereby providing an oral pouched nicotine product.

[0075] As disclosed herein, the moisture content of the oral pouched nicotine product in step b) may be within the range of from about 35 % by weight to about 55 % by weight, based on the total weight of the moist filling material.

[0076] It will be appreciated that the step of enclosing the moist filling material in a saliva permeable pouch may take place by measuring portions of the moist filling material and inserting the portions into a nonwoven tube.

[0077] The oral pouched products described herein are normally sized and configured to fit comfortably and discreetly in a user's mouth between the upper and lower gum and the lip.

[0078] In the method(s) described herein, the non-encapsulated flavouring agent such as the non-encapsulated non-particulate flavouring agent as described herein may be added after all other components have been mixed.

[0079] There is also provided a moist filling material as described herein which is obtainable by a method as described herein.

[0080] There is also provided an oral pouched nicotine product as described herein which is obtainable by a method as described herein.

EXAMPLE

General

[0081] The ethyl cellulose was provided as a powder from Aldrich Chemistry, Germany, and had an ethoxyl content of 48%. The monoglyceride was distilled monoglyceride from sunflower oil, and was provided as the product Dimodan® from Danisco, Denmark.

Abbreviations

[0082]

g	gram(s)
GC/MS	Gas Chromatography-Mass Spectroscopy
M	molar
ml	Milliliter(s)
N/mm	Newton per millimeter(s)
RH	relative humidity

[0083] In this example, the distribution of the flavour in the pouch material and the moist filling material of two oral pouched nicotine products was measured. The pouched products were also analysed with regard to seal strength.

[0084] Two wet compositions were prepared. In the wet composition denominated Sample 1, ethyl cellulose was present. In the wet composition denominated Reference, no ethyl cellulose was present. The ingredients and amounts of the ingredients of the wet compositions are shown in Table 1 below.

Table 1

Amount and percentage based on wet weight of composition				
Ingredient	Sample 1		Reference	
Microcrystalline cellulose (MCC)	729.5 g	40.5%	748.3	41.6%
Nicotine bitartrate dihydrate	62.8 g	3.5%	62.8 g	3.5%
Taste enhancers	63.9 g	3.6%	63.9 g	3.6%
pH regulators	63.9 g	3.5%	63.9 g	3.6%
Ethylcellulose	18.0 g	1.0%	-	-
Water and humectant	840.2 g	46.7%	839.5 g	46.6%
Liquid flavor mixture (containing menthol, menthone and carvone)	21.6 g	1.2%	21.6 g	1.2%

[0085] The compositions in Table 1 were produced using the following wet granulation. The dry ingredients microcrystalline cellulose, sodium chloride, nicotine bitartrate, sodium carbonate, calcium chloride, sweetener and if applicable ethyl cellulose were mixed for 3 minutes. Thereafter, the wet ingredients water and humectant were added during mixing and then the flavour was added. The total wet granulation time was about 10 min. The resulting moist filling material was thereafter portion-packed in a semi-permeable packaging material of nonwoven using heat-melt welding thereby providing oral pouched products.

[0086] The pouched products were thereafter stored in airtight containers at 25°C/60% RH for 30 days. The resulting pouches with content were analyzed with regard to flavour distribution. Flavour components menthone, menthol and carvone were used as markers for flavour.

[0087] Samples were extracted with a liquid-liquid extraction method (further described in the below). Extracts were analyzed with a GC/MS instrument (Agilent 7890/5975C). Quantification was done using an eight-point standard curve. The method has been verified for different matrices and the recoveries of analyte are better than 95%.

[0088] The weight of each oral pouch was noted. The paper was separated from the filling material and placed in different vials with each respective weight noted. 4 ml of 3 M NaOH was added to each extraction vial. The samples were shaken for 5 minutes at ambient temperature (360 rpm). Thereafter 10 ml of methyl tertiary butyl ether and internal standard were added. Samples were shaken for 60 minutes at 50° C (360 rpm). After cooling for one hour, the organic extracts were transferred to GC-vials and analyzed with GC/MS. Measuring ions for menthone, menthol and carvone were 112.10/139.10, 123.10/138.10 and 82.00/108.10 m/z.

[0089] The results are shown in Tables 2, 3 and 4 below. Each measured value is the average value of 3 analyzed samples.

Table 2

Menthone	Menthone in pouch material	Menthone in moist filling material
Sample 1	68%	32%
Reference	100%	0%

Table 3

Menthol	Menthol in pouch material	Menthol in moist filling material
Sample 1	54%	46%
Reference	95%	5%

Table 4

Carvone	Carvone in pouch material	Carvone in moist filling material
Sample 1	69%	31%

(continued)

Carvone	Carvone in pouch material	Carvone in moist filling material
Reference	97%	3%

[0090] It was observed that for the reference sample no or only 5 % of the flavour components remained in the filling material. In contrast, for Sample 1 more than 30 % of the flavour components remained in the moist filling material. It was observed that more flavour remained in the filling material when ethyl cellulose was present. Thus, the presence of ethyl cellulose led to improved retention of the flavour in the moist filling material.

[0091] The pouched products were also analysed with regards to pouch seal strength using the following method.

[0092] After one week storage in room temperature, the samples were prepared by cutting the pouches to a specified width (specified below) and opening the pouch so that one seal is left with two plies. The strength of the seal was then tested using an Instron 5943. One ply is attached to the upper gauge and one ply to the lower gauge. The force used to peel apart the seal was determined as average load per width expressed in N/mm. The following machine parameters were used:

load cell: 100 N
extension: 10 mm
gauge length: 13 mm
speed: 10 mm/min
preload: 0,1 N
sample width: 10 mm

[0093] The results are presented in Table 5 below. Each measured value is the average value of twelve analysed samples.

Table 5

	Peel strength (N/mm)
Sample 1	0.138
Reference	0.084

[0094] Sample 1 containing ethyl cellulose was found to have improved seal strength compared to the Reference.

Claims

1. An oral pouched nicotine product comprising a moist filling material and a saliva-permeable pouch of a packaging material enclosing the moist filling material, the moist filling material comprising:

   - a non-tobacco material;
   - a non-encapsulated flavouring agent;
   - a nicotine source;
   - a pH adjusting agent;
   - ethyl cellulose; and
   - optionally a tobacco material in an amount within the range of from 0.1 % to 10% by weight, based on the total weight of the moist filling material.

2. An oral pouched nicotine product according to claim 1, wherein the non-tobacco material comprises or consists of a particulate non-tobacco material, non-tobacco fibers or a mixture of a particulate non-tobacco material and non-tobacco fibers.

3. An oral pouched nicotine product according to claim 1 or 2, which is free from tobacco.

4. An oral pouched nicotine product according to claim 1 or 2, wherein the tobacco material is present in an amount within the range of from 0.1% to 10% by weight such as from 0.1% to 5% by weight, such as from 0.2% by weight

to 1% by weight based on the total weight of the moist filling material.

5. An oral pouched nicotine product according to any one of the preceding claims wherein the moist filling material has a moisture content within the range of from 10% to 60% by weight, such as from 40% to 60% by weight, such as from 35% to 55% by weight, such as from 35% to 50% by weight, such as from 30% to 40% by weight, or such as from 50% to 60% by weight, based on the total weight of the moist filling material.

6. An oral pouched nicotine product according to any one of the preceding claims, wherein the ethyl cellulose is present in an amount within the range of from 0.1% to 10% by weight, such as from 0.1% to 8% by weight, such as from 0.1% to 6% by weight, such as from 0.1% to 5% by weight, such as from 0.1 to 4 % by weight, such as from 0.1 to 3 % by weight, such as from 0.1 to 2 % by weight, such as from 0.5 % by weight to 1.5 % by weight, such as from 0.1 to 1 % by weight, based on the total weight of the moist filling material.

7. An oral pouched nicotine product according to any one of the preceding claims, wherein the moist filling material comprises within the range of from 30% to 80% by weight of the non-tobacco material, based on the total weight of the moist filling material.

8. An oral pouched nicotine product according to any one of the preceding claims, wherein the non-tobacco material comprises or consists of microcrystalline cellulose.

9. An oral pouched nicotine product according to any one of the preceding claims, wherein the nicotine source is present in an amount within a range of from 0.5% to 10% by weight calculated as nicotine base, based on the total weight of the moist filling material.

10. An oral pouched nicotine product according to any one of the preceding claims, wherein the nicotine source is selected from the group consisting of nicotine base, nicotine polacrilex, nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate, nicotine salicylate, and any combination(s) thereof.

11. An oral pouched nicotine product according to any one of the preceding claims, wherein the nicotine source is one or more of the following: nicotine bitartrate, nicotine bitartrate dihydrate, an aqueous solution comprising nicotine base and tartaric acid.

12. An oral pouched nicotine product according to any one of the preceding claims, wherein the moist filling material comprises one or more water-insoluble non-tobacco fibers selected from the group consisting of bamboo fibers, maize fibers, oat fibers, tomato fibers, barley fibers, rye fibers, sugar beet fibers, buck wheat fibers, wheat fibers, pea fibers, potato fibers, apple fibers, cocoa fibers, citrus fibers, and any combination thereof.

13. An oral pouched nicotine product according to any one of the preceding claims, wherein the moist filling material comprises bamboo fibres.

14. Use of ethyl cellulose for flavour preservation, prevention of pouch seal weakening and/or improved shelf life stability in an oral pouched nicotine product such as an oral pouched tobacco free nicotine product, an oral pouched low tobacco product and/or an oral pouched nicotine product as defined in any one of the preceding claims, such as flavour preservation, and/or improved shelf life stability at room temperature.

15. A method for manufacturing a moist filling material as defined in any one claims 1-13, the method comprising the steps of:

a) providing a mixture comprising a non-tobacco material and a nicotine source, and
b) adding water to the mixture comprising non-tobacco material and nicotine source,

wherein ethyl cellulose, a non-encapsulated flavouring agent, a pH adjusting agent and optionally a tobacco material independently are added in and/or after any of the foregoing steps.

16. A method for manufacturing an oral pouched nicotine product according to any one of claims 1-13, the method comprising the steps of:

a) providing a filling material as defined in any one of claims 1-13 or produced in accordance with claim 15, and
b) enclosing the filling material from step a) in a saliva-permeable pouch thereby providing an oral pouched nicotine product.

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EUROPEAN SEARCH REPORT

Application Number
EP 21 17 6442

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X Y	WO 2021/048792 A1 (REYNOLDS TOBACCO CO R [US]) 18 March 2021 (2021-03-18) * page 29, line 7 - line 13; claims 1,4,9,15,21,23,24,27,47 * * page 11, line 23 - line 26 * * page 9 - page 10 * -----	1-12, 14-16 13	INV. A24B13/00 A24B15/16 A24B15/28
Y	US 2020/383372 A1 (STAHL MY LY LAO [DK] ET AL) 10 December 2020 (2020-12-10) * page 4, line 4 - line 8 * -----	13	
A	CN 103 082 399 B (FANG LI) 4 February 2015 (2015-02-04) * paragraphs [0015], [0044]; claim 1 * -----	1-16	

TECHNICAL FIELDS SEARCHED (IPC)

A24B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	2 November 2021	Villányi Kelemen, K

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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02-11-2021

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2021048792 A1	18-03-2021	US 2021068446 A1	11-03-2021
		WO 2021048792 A1	18-03-2021
US 2020383372 A1	10-12-2020	US 2020383372 A1	10-12-2020
		US 2020383373 A1	10-12-2020
		US 2021329962 A1	28-10-2021
		WO 2020244721 A1	10-12-2020
		WO 2020244722 A1	10-12-2020
		WO 2020244723 A1	10-12-2020
		WO 2020244724 A1	10-12-2020
		WO 2020244725 A1	10-12-2020
CN 103082399 B	04-02-2015	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2004056363 A2 **[0005]**
- WO 2007104573 A2 **[0006]**
- WO 2010114445 A1 **[0007]**
- WO 2012134380 A1 **[0008]**
- US 9801409 B1 **[0009]**
- WO 2018197454 A1 **[0013]**
- WO 2019115778 A1 **[0014]**

Non-patent literature cited in the description

- Moisture in Tobacco. Official Methods of Analysis 966.02. AOAC (Association of Official Analytical Chemics), 1990 **[0026]**