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(54) **NON-TOBACCO, NICOTINE-CONTAINING COMPOSITION, METHOD FOR PREPARING THE SAME AND A NON-TOBACCO, NICOTINE-CONTAINING PRODUCT COMPRISING THE SAME**

(57) The present invention relates to a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; and a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%;

with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively; a method for preparing the same and a pouch type non-tobacco, nicotine-containing product comprising the same.

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Description

TECHNICAL FIELD

- 5 **[0001]** The present invention relates to a non-tobacco, nicotine-containing composition, to a method for preparing the same and to a non-tobacco, nicotine-containing product comprising the same.

BACKGROUND ART

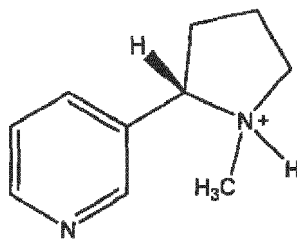
- 10 **[0002]** Moist snuff for oral use is available in loose form or portion-packed in a saliva- permeable, porous wrapper material forming a pouch. Pouched moist snuff is typically used by the user by placing the pouch between the upper or lower gum and the lip or cheek and retaining it there for 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 flavors and nicotine to diffuse from the tobacco material into the user's mouth.
- 15 **[0003]** However, the use of tobacco material in such products limits the organoleptic properties of these products. The tobacco material has a typical color, texture, smell and taste which may not always be attractive to the consumer. Further, tobacco material comprises constituents which may not be desirable in a pouched smokeless snus product.
- [0004]** A variety of non-tobacco, nicotine containing products for oral use is known in the art. For example, WO 2018/197454 A1 discloses an oral pouched nicotine product comprising a moist filling material including a particulate non-tobacco material, such as microcrystalline cellulose, a flavouring agent, a nicotine source and a pH adjusting agent.
- 20 **[0005]** WO 2019/115778 A1 discloses an oral pouched nicotine product comprising a moist filling material including a particulate non-tobacco material, such as microcrystalline cellulose, a non-encapsulated non-particulate flavouring agent, a nicotine source, a pH adjusting agent, and a monoglyceride. The oral pouched nicotine product may be free from tobacco or contain a small amount of tobacco.
- 25 **[0006]** However, non-tobacco, nicotine-containing compositions known in the art have the problem that a control of the release of nicotine from the compositions is insufficient. In particular, the nicotine is released from known compositions too fast leading to an unpleasant nicotine effect during administration including harshness, bitter taste, throat irradiation and hiccup.
- [0007]** Likewise, known compositions suffer from the problem that nicotine is already released in the composition causing oxidation of the nicotine base and an unpleasant brown-yellow-coloration.
- 30 **[0008]** A further drawback of compositions of the prior art is an unsatisfying shelf life particularly caused by moulding.
- [0009]** There is, however, still a need of improved non-tobacco, nicotine-containing compositions, in particular with respect to the taste (sweetness), nicotine release properties and shelf life thereof.
- [0010]** It is, therefore, an object of the present invention to provide a non-tobacco, nicotine-containing composition overcoming drawbacks of the prior art, in particular a non-tobacco, nicotine-containing compositions having improved sweetness, improved nicotine release properties and shelf life.
- 35

DISCLOSURE

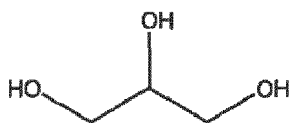
- 40 Non-tobacco, nicotine-containing composition

- [0011]** This object is, firstly, achieved by a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; and a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.
- 45 **[0012]** The term "non-tobacco" as referred to herein means that the composition is free of tobacco constituents. By "tobacco" as used herein is meant any part, e.g., leaves, stems, and stalks, of any member of the genus *Nicotiana* as a whole, shredded, threshed, cut, ground, cured, aged, fermented, or treated otherwise, e.g., granulated or encapsulated.
- [0013]** The term "nicotine-containing" as used herein means that the inventive composition comprises at least one nicotine source. As used herein, the term "nicotine source" refers to nicotine in any form.
- 50 **[0014]** The nicotine source may be liquid nicotine. The nicotine source may be a nicotine salt, preferably nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate, nicotine malate, nicotine tartrate, nicotine lactate, nicotine salicylate, or a mixture thereof. The nicotine source may be ion-exchange bound nicotine, preferably amberlite-bound nicotine such as nicotine polacrilex. Likewise, a nicotine source may be used which is a mixture of two or more of the before mentioned
- 55 nicotine sources.
- [0015]** The non-tobacco, nicotine-containing composition may comprise the nicotine source in an amount that the amount of nicotine is from 0.1 to 3.8 wt%, alternatively 0.2 to 3.5 wt%, alternatively 0.3 to 3.0 wt%, alternatively 0.4 to 2.5 wt%, alternatively 0.5 to 2.0 wt%, alternatively 0.6 to 1.8 wt%, alternatively 0.8 to 1.6 wt%, alternatively 0.9 to 1.5

wt%, alternatively 1.0 to 1.4 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition. The amount of nicotine in the non-tobacco, nicotine-containing composition is calculated based on the protonated form of nicotine



[0016] Glycerol is represented by the following formula



[0017] The non-tobacco, nicotine-containing composition may comprise the glycerol in an amount of 25 to 40 wt%, alternatively 25 to 35 wt%, alternatively 27 to 32 wt% with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0018] The water contained in the non-tobacco, nicotine-containing composition may be demineralized and/or sterilized. The non-tobacco, nicotine-containing composition may comprise the water in an amount 17 to 25 wt% with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0019] The non-tobacco, nicotine-containing composition may be for use in oral administration.

[0020] The total amount of all constituents of the non-tobacco, nicotine-containing composition, that is the different materials (for example, plant materials, chemical compounds etc.) forming the non-tobacco, nicotine-containing composition adds up to 100 wt%. The non-tobacco, nicotine-containing composition may comprise one or more further constituent. The non-tobacco, nicotine-containing composition may comprise two or further constituents. The non-tobacco, nicotine-containing composition may comprise at least one further solid constituent. In this regard, the term "solid constituent" refers to a constituent which is in the solid state under standard conditions, that is, normal pressure and room temperature (= 23 °C).

[0021] The one or more further constituent(s) which may be further comprised in the non-tobacco, nicotine-containing composition are independently selected from the following compounds.

Further constituents

[0022] The non-tobacco, nicotine-containing composition may further comprise isomaltulose (6-O- α -D-Glucopyranosyl-D-fructose). The non-tobacco, nicotine-containing composition may comprise isomaltulose in an amount of 0.1 to 20 wt%, alternatively 0.2 to 15 wt%, alternatively 0.5 to 10 wt%, alternatively 1 to 10 wt%, alternatively 2 to 10 wt%, alternatively 3 to 10 wt%, alternatively 4 to 10 wt%, alternatively 5 to 9 wt%, alternatively 6 to 8 wt%, alternatively about 7.5 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0023] The non-tobacco, nicotine-containing composition may further comprise a fiber-type and/or particulate plant material. The plant material may be water-insoluble.

[0024] The fiber-type and/or particulate plant material may be bamboo fiber, cocoa fiber, cane sugar fiber, hemp fiber, cereal fiber, preferably wheat fiber or oat fiber, potato fiber, vegetable fiber, preferably pea fiber or carrot fiber, fruit fiber, preferably lemon fiber or orange fiber, cellulose fiber, microcrystalline cellulose and mixtures thereof. The fiber-type and/or particulate plant material may be bamboo fiber.

[0025] The non-tobacco, nicotine-containing composition may comprise the fiber-type and/or particulate plant material in an amount of 0.1 to 50 wt%, alternatively 1 to 45 wt%, alternatively 5 to 40 wt%, alternatively 10 to 40 wt%, alternatively 20 to 40 wt%, alternatively 25 to 40 wt%, alternatively 30 to 40 wt%, alternatively 30 to 35 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0026] The non-tobacco, nicotine-containing composition may further comprise a sweetener. A "sweetener" is a food additive that provides a sweet taste like that of sugar while containing significantly less food energy than sugar-based sweeteners, making it a zero-calorie or low-calorie sweetener. The sweetener may be selected from the group consisting

of saccharin, sucralose, neotame and neohesperidine.

[0027] The non-tobacco, nicotine-containing composition may comprise the sweetener in an amount of 0.01 to 5 wt%, alternatively 0.05 to 2 wt%, alternatively 0.1 to 1.5 wt%, alternatively 0.2 to 1 wt%, alternatively 0.3 to 0.7 wt%, about 0.5 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0028] The non-tobacco, nicotine-containing composition may further comprise an acidity regulator (pH regulator, pH adjusting agent etc.). Acidity regulators, or pH control agents, are food additives used to change or maintain pH (acidity or basicity). They can be organic or mineral acids, bases, neutralizing agents, or buffering agents. The acidity regulator may be selected from the group consisting of sodium carbonate, potassium carbonate, calcium carbonate, sodium hydrogen carbonate, potassium hydrogen carbonate, calcium hydrogen carbonate, sodium hydroxide, potassium hydroxide, calcium hydroxide and mixtures thereof. The acidity regulator may be sodium carbonate.

[0029] The non-tobacco, nicotine-containing composition may comprise the acidity regulator in an amount of 0.1 to 10 wt%, alternatively 0.5 to 5 wt%, alternatively 1 to 4 wt%, alternatively 1.5 to 3.5 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0030] The non-tobacco, nicotine-containing composition further comprises glycyrrhizinic acid, a salt thereof or a mixture thereof. Glycyrrhizinic acid is a white solid the chief sweet-tasting constituent of *Glycyrrhiza glabra* (licorice) root. Glycyrrhizinic acid is further characterized by a specific licorice-type taste.

[0031] The non-tobacco, nicotine-containing composition may comprise the glycyrrhizinic acid, a salt thereof or a mixture thereof in an amount of 0.1 to 1 wt%, alternatively 0.3 to 1 wt%, alternatively 0.5 to 0.9 wt%, alternatively 0.7 to 0.9 wt%, alternatively about 0.8 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0032] The non-tobacco, nicotine-containing composition further comprises an inorganic filler. The inorganic filler may be selected from the group consisting of calcium silicate, magnesium silicate, aluminium silicate, magnesium oxide, calcium carbonate, magnesium carbonate, silicon dioxide.

[0033] The non-tobacco, nicotine-containing composition may comprise the inorganic filler in an amount of 1 to 20 wt%, alternatively 2 to 10 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0034] The non-tobacco, nicotine-containing composition further comprises a stabilizer. The stabilizer may be a poly(meth)acrylic resin. The stabilizer may be, for example, Amberlite IRP64, Purolite C115HMR oder Doshion P551. The non-tobacco, nicotine-containing composition may comprise the stabilizer in an amount of 1 to 10 wt% with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0035] The non-tobacco, nicotine-containing composition further comprises polyethylene glycol. The non-tobacco, nicotine-containing composition may comprise the polyethylene glycol in an amount of 0.1 to 10 wt%, alternatively 1 to 5 wt, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0036] The non-tobacco, nicotine-containing composition may further comprise a sugar substitute. The sugar substitute may be selected from sorbitol, maltitol, xylitol and a mixture thereof.

[0037] The non-tobacco, nicotine-containing composition may comprise the sugar substitute in an amount of 0.01 to 5 wt%, alternatively 0.05 to 2 wt%, alternatively 0.1 to 1.5 wt%, alternatively 0.2 to 1 wt%, alternatively 0.3 to 0.7 wt%, about 0.5 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0038] The non-tobacco, nicotine-containing composition may further comprise a flavouring agent. "Flavouring agent" is used herein for a substance used to influence the aroma and/or taste of the non-tobacco, nicotine-containing composition, including, but not limited to, essential oils, single flavour compounds, compounded flavourings, and extracts. The flavouring agent may be selected from the group of nature-identical and synthetic flavouring agents. In particular, the flavouring agent may be selected from the group consisting of menthol, vanillin, peppermint oils, eucalyptus oil, citrus oils, fruit aromas, preferably apple, blueberry, strawberry, raspberry, cherry, coconut, mango, melon, peach, coffee (in all variations from cappuccino to latte), spirits, preferably whisky or rum, sweet-creamy flavours, preferably toffee, popcorn, caramel, chocolate or cream, and spicy flavours, preferably pepper, chili, ginger, cinnamon, cocoa bean, coffee bean and a mixture thereof.

[0039] The non-tobacco, nicotine-containing composition may comprise the flavouring agent in an 0.01 to 10 wt%, alternatively 0.05 to 8 wt%, alternatively 0.1 to 7 wt%, alternatively 1 to 6 wt%, alternatively 3 to 5 wt%, about 4 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

[0040] The non-tobacco, nicotine-containing composition further comprises a taste improving agent, preferably selected from sodium chloride, ammonium chloride and a mixture thereof. The non-tobacco, nicotine-containing composition may comprise the taste improving agent in an 0.01 to 7.5 wt%, alternatively 0.05 to 5 wt%, alternatively 0.1 to 3 wt%, alternatively 0.2 to 2.5 wt%, alternatively 1 to 2 wt%, about 1.5 wt%, with respect to the total weight of the non-tobacco, nicotine-containing composition.

Exemplary embodiments

[0041] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; and a 0.1

to 50 wt% fiber-type and/or particulate plant material; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

[0042] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; 0.1 to 50 wt% fiber-type and/or particulate plant material; and 0.1 to 10 wt% acidity regulator; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

[0043] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; 0.1 to 50 wt% fiber-type and/or particulate plant material; 0.1 to 10 wt% acidity regulator; and 0.001 to 10 wt% flavouring agent; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

[0044] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; 0.1 to 20 wt% isomaltulose; and a 0.1 to 50 wt% fiber-type and/or particulate plant material; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

[0045] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; 0.1 to 20 wt% isomaltulose; 0.1 to 50 wt% fiber-type and/or particulate plant material; and 0.1 to 10 wt% acidity regulator; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

[0046] In one embodiment, there is provided a non-tobacco, nicotine-containing composition comprising 25 to 45 wt% glycerol; 15 to 25 wt% water; a nicotine source in an amount that the amount of nicotine is from 0.1 to 4 wt%; 0.1 to 20 wt% isomaltulose; 0.1 to 50 wt% fiber-type and/or particulate plant material; 0.1 to 10 wt% acidity regulator; and 0.001 to 10 wt% flavouring agent; with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

Method for preparing the non-tobacco, nicotine-containing composition

[0047] The object is further achieved by a method for preparing the non-tobacco, nicotine-containing composition as defined herein, the method comprising the steps:

a) providing a mixture of the nicotine source and at least one further solid constituent of the non-tobacco, nicotine-containing composition in a mixer having at least one cutter head;

b) spraying of water or an aqueous solution onto the mixture provided in the mixer having at least one cutter head and mixing with a rotational speed of the mixer having at least one cutter head of 10 to 500 rpm for 10 seconds to 30 minutes;

c) heating glycerol to a temperature from 30 to 40 °C; and

d) spraying the heated glycerol onto the mixture obtained in step b) and mixing with a rotational speed of the mixer having at least one cutter head of 10 to 500 rpm for 10 seconds to 30 minutes at a temperature from 25 to 35 °C.

[0048] The further solid constituent (respectively the further solid constituents) which may be used in step a) may be selected from a fiber-type and/or particulate plant material, isomaltulose, a sweetener, a solid flavouring agent, a solid taste improving agent, an inorganic filler or a mixture thereof. The further solid constituent (respectively the further solid constituents) which may be used in step a) may be a mixture comprising a fiber-type and/or particulate plant material, isomaltulose and a sweetener. The further solid constituents may be a mixture of plant fiber, sodium chloride, isomaltulose and sweetener.

[0049] The mixer having at least one cutter head may comprise a cylindrical drum, a shaft arranged horizontally in the center of the cylindrical drum. The at least one cutter head may be arranged on the shaft allowing the outermost end thereof to rotate close to the wall of the cylindrical drum.

[0050] The mixer having at least one cutter head may be a ploughshare mixer. The ploughshare shovels of the ploughshare mixer may be arranged on a mixing shaft in a horizontal, cylindrical drum rotate closely to the wall. Their peripheral speed and geometric form may selected in such a way to move out a product contained the product bed of the ploughshare mixer against the centrifugal force and in axial direction at the same time. In addition, the shape of the shovels may be selected to allow lifting the product from the drum wall. The mixing elements may have a shape and an arrangement on the shaft to ensure not only a reliable product conveyance but also a sufficient back-mixing of the product. The so-called "mechanical" fluid bed generated in this way, whereby the product is constantly involved in the process, ensures a maximum mixing intensity at even high throughputs and short residence times until the product is

discharged out of the mixer via an outlet. Suitable plowshare mixers are well known in the art and commercially available, for example from the supplier Gebrüder Lödige Maschinenbau GmbH, ploughshare® mixers for batch operation.

[0051] The aqueous solution which may be sprayed onto the mixture provided in the mixer having at least one cutter head may comprise (besides the water as a solvent) any water-soluble constituent of the non-tobacco, nicotine-containing composition. The aqueous solution may comprise the acidity regulator. The aqueous solution may be an aqueous sodium carbonate solution.

[0052] The aqueous solution may be sprayed onto the mixture using conventional spraying methods, for example, providing the aqueous solution in a pressure resistant container, the pressure resistant container being arranged above the mixer, and spraying the aqueous solution using compressed air with the pressure of at least 3 bar.

[0053] The mixing in step b) may be for 10 seconds to 30 minutes, alternatively 15 seconds to 20 minutes, alternatively 20 seconds to 15 minutes, alternatively 30 seconds to 5 minutes. ,

[0054] The mixing in step b) may be 10 to 400, alternatively 20 to 300 rpm, alternatively 30 to 200 rpm, alternatively 50 to 160 rpm, with respect to the rotational speed of the rotational shaft.

[0055] The glycerol may be heated to a temperature from 30 to 40 °C outside the mixer, for example in a climatic chamber, a climatic room, a water bath etc. The glycerol may be heated to a temperature from 31 to 39 °C, alternatively 32 to 38 °C, alternatively 33 to 37 °C, alternatively 34 to 36 °C, alternatively about 35 °C.

[0056] The mixing in step d) may be for 10 seconds to 30 minutes, alternatively 15 seconds to 20 minutes, alternatively 20 seconds to 15 minutes, alternatively 30 seconds to 5 minutes.

[0057] The mixing in step d) may be 10 to 400, alternatively 20 to 300 rpm, alternatively 30 to 200 rpm, alternatively 50 to 160 rpm, with respect to the rotational speed of the rotational shaft.

[0058] In step b) and/or step d), the rotational speed of the cutter head may be 1,000 to 5,000 rpm, alternatively 2,000 to 4,000 rpm, alternatively about 3,000 rpm.

[0059] The method may further comprise a step e) after the step d), wherein step e) comprises spraying a flavoring agent, a solution containing the flavoring agent or a mixture thereof onto the composition obtained in step d).

Pouched product

[0060] Finally, the object is achieved by a non-tobacco, nicotine-containing product comprising a pouch-type package and a non-tobacco, nicotine-containing composition as defined herein arranged in the pouch-type package ("pouched product" of the non-tobacco, nicotine-containing composition).

[0061] The non-tobacco, nicotine-containing product may be for oral use. The pouch-type package may be a saliva-permeable pouch material. The pouch of the non-tobacco, nicotine-containing product may be made of any suitable saliva-permeable (and preferably non-dissolvable) pouch material, such as non-woven. A binder may be included in the packaging material to facilitate sealing of the material by ultrasonic welding. The pouch material may be a nonwoven material comprising staple fibers of regenerated cellulose, such as viscose rayon staple fibers, and a binder, such as a polyacrylate.

[0062] The oral use of the non-tobacco, nicotine-containing product may comprise placing the non-tobacco, nicotine-containing product into the oral cavity, most commonly between the lower gum and lip or upper gum and lip. By contact with the saliva, constituents of the non-tobacco, nicotine-containing composition may elute from the pouch-type package and are consumed by the consumer. The use may further comprise easy chewing of the non-tobacco, nicotine-containing product, in particular at the beginning of the use.

ADVANTAGEOUS EFFECTS

[0063] A crucial aspect of the present invention is to provide a non-tobacco, nicotine-containing composition having a (relatively) low water content and having a (relatively) high glycerol content. By the high amount of glycerol and the low amount of water (in particular far below 30 wt%) in the inventive non-tobacco, nicotine-containing composition slow release of nicotine can be achieved. In this regard, "slow release" refers to both the release during administration of a product comprising the composition in the oral cavity as well as release before administration in the composition. This slow release of nicotine can be further supported by an acidity regulator providing a suitable pH value, preferably between 7 and 8 .

[0064] The high amount of glycerol were further found to be helpful to provide a usual (natural) "wet mouth feeling" despite the missing water content.

[0065] Furthermore, the low water content is helpful to avoid or reduce moulding of the composition comprising the same.

[0066] In addition, the use of high amounts of glycerol (having a slightly sweet taste) supports the overall sweetness of the product. Moreover, the consume of glycerol is safe even in large amounts. Finally, glycerol supports the reception and distribution of flavoring agents.

[0067] The further use of isomaltulose in the non-tobacco, nicotine-containing composition can be used as a density-enhancing filler which facilitates filling the composition into small pouches.

[0068] In addition the use of isomaltulose in the non-tobacco, nicotine-containing composition has a positive effect on the sweet taste of the composition without a cariogenic effect.

[0069] In the inventive method, the combination of the mixer having at least one cutter head and the spraying of heated glycerol allows surprisingly to achieve a particularly homogeneous non-tobacco, nicotine-containing composition. The use of the at least one cutter head, in particular with the specific rotational speed, is helpful to prevent clumping of the constituents (including the glycerol) during preparation of the non-tobacco, nicotine-containing composition and supports a homogeneous distribution of the water (respectively the aqueous solution) and/or the flavouring agents.

DETAILED DESCRIPTION

[0070] Reference will now be made in detail to the exemplary embodiments of the present invention. The exemplary embodiments are described below, in order to explain the aspects of the present invention without, however, necessarily limiting the invention thereto. Nevertheless specific aspects thereof may, together with general aspects described herein for the disclosure of the invention, be material for realizing embodiments of the invention.

General preparation route

[0071] A mixture comprising nicotine polacrilex as a nicotine source, bamboo fiber, sodium chloride, and optionally further solid ingredients as listed in below Tables 1 to 3 was provided in a ploughshare mixer (Gebrüder Lödige Maschinenbau GmbH, ploughshare® mixer for batch operation) and slowly mixed with a rotational speed of 50 rpm for 1 minute without using the cutter head of the mixer.

[0072] An aqueous solution of sodium carbonate (acidity regulator) in demineralized and sterilized water was sprayed onto the obtained mixture followed by vigorous mixing using the cutter head of the ploughshare mixer at a rotational speed of 160 rpm for 2 minutes.

[0073] Glycerol was heated in a climatic room to 35 °C. The heated glycerol was sprayed onto the mixture obtained in the ploughshare mixer mixture followed by vigorous mixing using the cutter head of the ploughshare mixer at a rotational speed 160 rpm of for 5 minutes.

[0074] A mixture of menthol/eucalyptus and spearmint was heated in a climatic chamber to 35 °C. The heated menthol/eucalyptus and spearmint mixture was sprayed onto the mixture obtained in the ploughshare mixer mixture followed by vigorous mixing using the cutter head of the ploughshare mixer at a rotational speed of 160 rpm for 2 minutes.

[0075] During all of the process steps, the temperature within the ploughshare mixer was controlled below 35°C.

[0076] The amounts of the different ingredients were selected for different compositions as set forth below in Tables 1 to 3.

[0077] The finished product was packed into small pouches using a common packaging machine.

Example 1

[0078] A non-tobacco, nicotine-containing composition with high sodium carbonate content, pH 8.2 and 1.4 wt% nicotine was prepared in accordance with Table 1.

Table 1:

	Amount [kg]	Amount (wt%)
Glycerol	20.63	27.50
Water	18.75	25.00
Bamboo fiber	24.75	32.50
Sucralose	0.38	0.50
Sodium carbonate	2.25	3.50
Nicotine polacrilex (20%)	5.25	7.00
Flavouring agent	3.00	4.00

[0079] A strong nicotine-induced effect was observed for oral administration of the composition of Example 1.

Example 2

[0080] A non-tobacco, nicotine-containing composition with low sodium carbonate content, pH 7.8 and 1.2 wt% nicotine was prepared in accordance with Table 2.

Table 2:

	Amount [kg]	Amount (wt%)
Glycerol	20.63	30.25
Water	13.88	17.5
Bamboo fiber	22.69	30
Isomaltulose	6.38	7.50
Sodium chloride	1.50	1.50
Sucralose	0.38	0.50
Sodium carbonate	2.06	2.75
Nicotine polacrilex (20%)	4.50	6.00
Flavouring agent	3.00	4.00

[0081] A moderate nicotine-induced effect was observed for oral administration of the composition of Example 2. An intense sweet taste was observed for oral administration of the composition of Example 2.

Example 3

[0082] A non-tobacco, nicotine-containing composition with low sodium carbonate content, pH 7.1 and 1.0 wt% nicotine was prepared in accordance with Table 3.

Table 3:

Aromen/Zusatzstoffe	Amount [kg]	Amount (wt%)
Glycerol	20.63	27.50
Water	13.88	17.50
Bamboo fiber	22.50	34.20
Sodium chloride	5.63	7.50
Glycyhrrizine	0.75	0.80
Ammonium chloride	2.25	2.00
Sodium carbonate	1.13	1.50
Nicotine polacrillex (20%)	5.25	5.00
Flavouring agent	3.00	4.00

[0083] A slow and low nicotine-induced effect was observed for oral administration of the composition of Example 3. The taste is more "traditional" because of the use of a high amount sodium chloride and the licorice taste from Glycyhrrizine and its enhancer Ammonium chloride.

Comparative Example 1

[0084] A non-tobacco, nicotine-containing composition was prepared as described for Example 1 with the only exceptions that a high water content and a lower glycerin content was used in accordance with Table 4.

Table 4:

	Amount [kg]	Amount (wt%)
Glycerol	15.00	20.00
Water	24.37	32.50
Bamboo fiber	24.75	32.50
Sucralose	0.38	0.50
Sodium carbonate	2.25	3.50
Nicotine polacrillex (20%)	5.25	7.00
Flavouring agent	3.00	4.00

[0085] An unpleasantly high nicotine-induced effect was observed at the beginning of the oral administration of the composition of Comparative Example 1 which may be released to an unwanted fast release of high amounts of nicotine immediately after the start of oral administration.

[0086] In addition, the taste of the product was unpleasantly due to a perceptible nicotine tast (which might be traced back to an insufficient sweetness for masking of the nicotine taste).

[0087] Furthermore, it was found that the composition of Comparative Example 1 showed a lowered shelf life with respect to moulding during storage in comparison to the composition of Example 1.

Comparative Example 2

[0088] A non-tobacco, nicotine-containing composition was prepared as described for Example 1 with the only exceptions that a lower water content and a higher glycerin content was used in accordance with Table 5.

Table 5:

	Amount [kg]	Amount (wt%)
Glycerol	37.50	50.00
Water	1.87	2.50
Bamboo fiber	24.75	32.50
Sucralose	0.38	0.50
Sodium carbonate	2.25	3.50
Nicotine polacrilex (20%)	5.25	7.00
Flavouring agent	3.00	4.00

[0089] It was not possible to manufacture a product suitably for oral administration from a respective composition due to its stickiness and caking during the mixing.

Comparative Example 3

[0090] A mixture comprising nicotine polacrilex as a nicotine source, bamboo fiber, sodium chloride, and optionally further solid ingredients as listed in below Tables 1 to 3 was provided in a vat and slowly mixed by shaking the vat.

[0091] An aqueous solution of sodium carbonate (acidity regulator) in demineralized and sterilized water was sprayed onto the obtained mixture followed by shaking.

[0092] Glycerol was heated in a climatic room to 35 °C. The heated glycerol was sprayed onto the mixture obtained in the ploughshare mixer mixture followed by shaking.

[0093] A mixture of menthol/eucalyptus and spearmint was heated in a climatic chamber to 35 °C. The heated glycerol was sprayed onto the mixture obtained in the ploughshare mixer mixture followed by shaking.

[0094] During all of the process steps, the temperature within the vat was controlled below 35°C.

[0095] The amounts of the different ingredients were selected for different compositions as set forth below in Table 1.

[0096] The obtained product exhibited a high degree of clumping as well as low homogeneity and was inappropriate for preparing a pouch- type product.

[0097] The features disclosed in the foregoing description and in the dependent claims may, both separately and in any combination thereof, be material for realizing the aspects of the disclosure made in the independent claims, in diverse forms thereof.

Claims

1. Non-tobacco, nicotine-containing composition comprising

- 25 to 45 wt% glycerol;
- 15 to 25 wt% water; and
- a nicotine source containing 0.1 to 4 wt% nicotine or a precursor thereof;

with respect to the total weight of the non-tobacco, nicotine-containing composition, respectively.

2. Non-tobacco, nicotine-containing composition according to claim 1, wherein the non-tobacco, nicotine-containing composition further comprises isomaltulose in an amount of 0.1 to 10 wt% with respect to the total weight of the non-tobacco, nicotine-containing composition.
3. Non-tobacco, nicotine-containing composition according to claim 1, wherein the non-tobacco, nicotine-containing composition further comprises a fiber-type and/or particulate plant material, preferably selected from the group consisting of bamboo fiber, cocoa fiber, cane sugar fiber, hemp fiber, cereal fiber, particularly preferred wheat fiber or oat fiber, potato fibres, vegetable fibres, particularly preferred pea fibres or carrot fibres, fruit fibres, particularly preferred lemon fibres or orange fibres, cellulose fibres, microcrystalline cellulose and mixtures thereof.
4. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the nicotine source is selected from the group consisting of liquid nicotine, a nicotine salt, preferably nicotine malate, nicotine tartrate, nicotine nitrate, nicotine lactate or nicotine salicylate, ion-exchange bound nicotine or a mixture thereof.
5. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises a sweetener, preferably selected from the group consisting of saccharin, sucralose, neotame and neohesperidine.
6. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises an acidity regulator, preferably selected from the group consisting of sodium carbonate, potassium carbonate, calcium carbonate, sodium hydrogen carbonate, potassium hydrogen carbonate, calcium hydrogen carbonate, sodium hydroxide, potassium hydroxide, calcium hydroxide and mixtures thereof.
7. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises glycyrrhizinic acid, a salt thereof or a mixture thereof.
8. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises an inorganic filler.
9. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises a sugar substitute, preferably selected from sorbitol, maltitol, xylitol and a mixture thereof.
10. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises a flavouring agent, preferably selected from the group consisting of menthol, vanillin, peppermint oils, eucalyptus oil, citrus oils, fruit aromas, preferably apple, blueberry, strawberry, raspberry, cherry, coconut, mango, melon, peach, coffee (in all variations from cappuccino to latte), spirits, preferably whisky or rum, sweet-creamy flavours, preferably toffee, popcorn, caramel, chocolate or cream, and spicy flavours, preferably pepper, chili, ginger, cinnamon, cocoa bean, coffee bean and a mixture thereof.
11. Non-tobacco, nicotine-containing composition according to any of the preceding claims, wherein the non-tobacco, nicotine-containing composition further comprises a taste improving agent, preferably selected from sodium chloride, ammonium chloride and a mixture thereof.
12. A method for preparing the non-tobacco, nicotine-containing composition according to any of the preceding claims, the method comprising the steps:
 - a) providing a mixture of the nicotine source and at least one further solid constituent of the non-tobacco, nicotine-containing composition in a mixer having at least one cutter head;
 - b) spraying of water or an aqueous solution onto the mixture provided in the mixer having at least one cutter head and mixing with a rotational speed of the mixer having at least one cutter head of 10 to 500 rpm for 10 seconds to 30 minutes;
 - c) heating glycerol to a temperature from 30 to 40 °C; and
 - d) spraying the heated glycerol onto the mixture obtained in step b) and mixing with a rotational speed of the mixer having at least one cutter head of 10 to 500 rpm for 10 seconds to 30 minutes; at a temperature from 25

to 35 °C.

13. Method according to claim 12, wherein the mixer having at least one cutter head is a ploughshare mixer.

5 14. Method according to claim 12 or 13, wherein the method comprises a further step e) after the step d), wherein step e) comprises spraying a flavoring agent, a solution containing the flavoring agent or a mixture thereof onto the composition obtained in step d).

10 15. Non-tobacco, nicotine-containing product comprising a pouch-type package and a non-tobacco, nicotine-containing composition according to any one of the claims 1 to 11 arranged in the pouch-type package.

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EUROPEAN SEARCH REPORT

Application Number
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