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(54) **AN ORAL NICOTINE PRODUCT COMPRISING A PH ADJUSTING AGENT**

ORALES NIKOTINPRODUKT MIT PH-EINSTELLUNGSMITTEL

PRODUIT ORAL À BASE DE NICOTINE COMPRENANT UN AGENT D'AJUSTEMENT DU PH

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EP 3 917 339 B1

Description

TECHNICAL FIELD

[0001] The present disclosure relates to an oral pouched nicotine product comprising no tobacco or a small amount of tobacco and use of a pH adjuster for counteracting an increase in pH when said product is stored.

BACKGROUND

[0002] Traditionally, oral smokeless tobacco products are used in the oral cavity of a consumer to provide nicotine satisfaction from the tobacco in the product. In addition to the tobacco, the oral smokeless tobacco product generally comprises water, salt, pH adjuster(s) and additional ingredients such as flavours and humectants. Commonly, these products are called snuff. The snuff may be dry or moist, and may be provided in loose form or in pouched form. Moist snuff is divided into two types, namely American snuff and Scandinavian snuff. American moist snuff is commonly produced through a fermentation process of moisturized ground or cut tobacco. Scandinavian-type moist snuff (snus) is commonly produced using a heat-treatment process (pasteurization) instead of fermentation. The heat treatment is carried out in order to degrade, destroy or denature at least a portion of the organisms within the tobacco preparation.

[0003] Oral pouched nicotine products comprising no tobacco or a small amount of tobacco are now becoming increasingly popular among consumers due to inter alia their appealing appearance, freshness and taste. Moreover, this kind of product allows a user to enjoy nicotine without being exposed to tobacco.

[0004] US2018/271139 discloses an oral pouched smokeless tobacco product which generally includes a tobacco composition comprising divided (e.g. ground or cut) tobacco material, water, salt (e.g. sodium chloride, potassium chloride, magnesium chloride, calcium chloride or any combinations thereof), pH adjuster (e.g. sodium carbonate, sodium hydroxide, potassium hydroxide, potassium carbonate, sodium carbonate, sodium bicarbonate or magnesium carbonate) and optionally one or more additional ingredients. The salt is added mainly for its effect on taste but it also has a preservative action which contributes to improved shelf life of the product. Salt, such as sodium chloride lowers the water activity of the products, thus preventing micro-organisms from growing.

[0005] WO 2012/134380 discloses a pouch containing nicotine in free salt form, i.e. an oral pouched nicotine-containing non-tobacco snuff product. The product comprises 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, wherein said pouch is permeable for saliva and therein dissolved parts of the powder, wherein said product upon contact with purified water gives a pH of at least 6.

[0006] EP 3 087 852 discloses an oral pouched product having a rectangular shape. The oral pouched product may be an oral pouched non-tobacco nicotine-containing snuff product. The filling material of the product may be a particulate material comprising nicotine or a salt thereof and one or more fillers, such as polysaccharides and/or microcrystalline cellulose. It is stated that salt, such as sodium chloride, potassium chloride, magnesium chloride, calcium chloride and any combinations thereof, may be added mainly for its effect on taste but it also has a preservative action which contributes to improved shelf life of the product. Salt, such as sodium chloride, lowers the water activity of the products, thus preventing microorganisms from growing.

[0007] pH is known to contribute to regulating the uptake of nicotine through the mucous membranes in the oral cavity of a consumer, such as a human. A pH adjusting agent is needed to increase the amount of nicotine present in the form of a free base, which may be absorbed through the mucous membranes in the oral cavity of a consumer. However, an alkaline pH reduces nicotine extraction from the product. In particular, a very high pH has a negative effect on the taste of the product and is also detrimental for the oral mucous membranes. On the other hand, an acidic pH improves nicotine mobility and extraction from the product, but diminishes nicotine uptake in the oral cavity and is bad for oral health. Consequently, it is frequently desired to adjust the pH of oral pouched nicotine products to be neutral or slightly alkaline such as from pH 7 to 10. Commonly, this is achieved using pH adjusters comprising sodium carbonate and/or sodium bicarbonate.

[0008] Unfortunately, the pH of snuff products such as oral smokeless tobacco snuff products has been found to drop upon storage. In order to counteract the pH drop the product may be kept refrigerated and/or the amount of sodium carbonate and/or sodium bicarbonate may be increased. However, this makes handling of the product less convenient, and may affect the taste of the product in an undesired way.

[0009] WO 2009/082331 discloses a tobacco or non-tobacco product comprising magnesium carbonate for conferring pH stability to the product and preventing growth of bacteria and fungi therein.

[0010] WO 2015/193379 discloses a tobacco or non-tobacco product comprising magnesium carbonate. The composition is enclosed by a wrapping material, which comprises magnesium carbonate. In this way, the oral pH is stabilized during use of said product. Figure 1 shows that the oral pH during use of oral smokeless tobacco products drops during use.

[0011] WO 2018/233795 discloses a nicotine pouch containing a matrix composition comprising a combination of nicotine and a water-soluble composition.

[0012] Thus, there is a need for oral pouched nicotine products comprising no tobacco or a small amount of tobacco, in which products the pH upon storage does not change, changes to a limited extent and/or remains within a range from about 7 to about 10.

[0013] An object of the present disclosure is to alleviate at least one of the problems discussed above, and to provide advantages and aspects not provided by hitherto known technique. Further, it is an object of the present disclosure to prevent, reduce and/or counteract a change in pH such as an increase in pH in an oral pouched nicotine product comprising no tobacco or a small amount of tobacco.

SUMMARY

[0014] The present disclosure provides an oral pouched nicotine product comprising a filling material and a saliva-permeable pouch of a packaging material enclosing the filling material, the filling material comprising or consisting of:

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from 1 wt% to 45 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising or consisting of:

  (i) Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
  (ii) a salt of Formula (I):

$$m^{2+}(A^{n-})_m \qquad \text{Formula I}$$

  or a hydrate of said salt,
  wherein

  M^{2+} is selected from the group consisting of Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} and Fe^{2+},
  A^{n-} is an anion selected from the group consisting of chloride, lactate, malate, succinate, citrate, ascorbate, tartrate, acetate, phosphate, sulphate, nitrate, gluconate, alginate, oxalate, aspartate, glycinate, picolinate, oxide cysteinate, glutamate, hydroxide, laurate, stearate, palmitate, undecylenate, gluceptate, glucerophosphate, glubionate, glucoheptonate, guanylate, inosinate, propionate, sorbate, salicylate, benzoate, erythorbate, formate, iodide, pangamate and any combination thereof,
  n is 1 or 2,
  m is 1 or 2, and

- $(n \times m) = -2$,

  said salt being present in an amount within the range of from 0.05 wt% to 5 wt%, based on the total weight of the filling material,
  said salt having a water solubility equal to or above about 0.04 M and/or equal to or above 1 g/L, and

- optionally a tobacco material in an amount within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material,

wherein the pH of said filling material of said oral pouched nicotine product does not exceed 9.5 upon storage and/or changes by no more than 0.5 pH units upon storage, such as storage taking place at a relative humidity from 60% to 75%, at a temperature from 22°C to 30°C, and/or for a time of 15 weeks.

[0015] The present disclosure also provides a use of a salt of Formula I, or a hydrate of said salt, as described herein for controlling pH in an oral pouched nicotine product comprising a filling material, said filling material comprising:

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from 1 wt% to 45 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising or consisting of Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
- optionally a tobacco material within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material,

when said product is stored, such as stored

at a relative humidity from 60% to 75%,
at a temperature from 22°C to 30 °C, and/or
for a time of 15 weeks.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016]

Figure 1 shows the pH value (pH units) as a function of storage time (weeks) for dry oral pouched nicotine products comprising no $CaCl_2$ or increasing amounts of $CaCl_2$, when storage was performed at a temperature of 30°C, and a relative humidity of 75%.
Figure 2 shows the pH value (pH units) as a function of storage time (weeks) for two samples of snus when storage is performed at a temperature of 22 °C and a relative humidity of 60 %.
Figure 3 shows the pH value (pH units) as a function of storage time (weeks) for moist oral pouched nicotine products comprising no $CaCl_2$ or increasing amounts of $CaCl_2$, when storage was performed at a temperature of 22°C and a relative humidity of 60%.

DESCRIPTION

[0017] The term "tobacco material" is used herein for tobacco extract and/or fibrous material of tobacco leaves or parts of tobacco 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.

[0018] 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.

[0019] "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.

[0020] 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. Some fibrous materials may exhibit hygroscopic properties. Hygroscopic materials maintain equilibrium moisture content depending on the ambient moisture and temperature. 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 (RH) 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.

[0021] "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.

[0022] As used herein "% w/w", "w/w %", "wt%", "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.

[0023] 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.

[0024] 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".

[0025] 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. Two examples of oral pouched nicotine products are oral pouched nicotine non-tobacco products and oral pouched low

tobacco nicotine products.

[0026] As used herein the terms "oral pouched nicotine non-tobacco product", "oral pouched tobacco free nicotine product" or "oral pouched nicotine product free from tobacco" 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.

[0027] As used herein the term "oral pouched low tobacco 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.

[0028] As used herein, the term "non-particulate" refers to a component which is not in particulate form. For instance, the flavouring agent described herein may be a non-particulate flavouring agent such as a liquid, an oil or a mixture thereof.

[0029] As used herein, the term "particulate non-tobacco material" refers to a non-tobacco material comprising particles. The particles may have an average particle size within the range of from 50 to 500 μm.

[0030] The oral pouched nicotine product as disclosed herein is intended for use in the oral cavity, such as by buccal placement (e.g. by placing the pouched product between the upper or lower gum and the lip or cheek), and may therefore be referred to as portion-packed (pouched) product for oral use. The oral pouched nicotine product is sized and configured to fit comfortably and discreetly in a user's mouth between the upper or lower gum and the lip or cheek.

[0031] The oral pouched nicotine product as disclosed herein may have an oblong shape, such as a substantially rectangular shape (as seen from above when the product is placed on a planar surface). In such case, the longitudinal direction of the product corresponds to the length of the substantially rectangular product and the transverse direction of the product corresponds to the width of the substantially rectangular product.

[0032] The total weight of the oral pouched nicotine product (including filling material and packaging material) may be within the range of from about 0.3 to about 1.5 g.

[0033] The filling material of the oral pouched nicotine product described herein may be provided as a powder or granulate. Thus, the filling material enclosed by the saliva-permeable pouch of the packaging material may be provided in a non-compressed form.

[0034] The pouch of the oral pouched nicotine product may be made of any suitable saliva-permeable (and preferably non-dissolvable) packaging material, such as a non-woven material. The packaging material (herein also called pouch material) may be a nonwoven material comprising staple fibres of regenerated cellulose, such as viscose rayon staple fibres, and a binder, such as a polyacrylate.

[0035] The oral pouched (i.e. portion-packed) nicotine products may be positioned randomly in a container or in a pattern, for instance as described in WO 2012/069505. Alternatively or additionally, each oral pouched nicotine product may be placed in a sachet.

[0036] The present disclosure provides an oral pouched nicotine product comprising a filling material and a saliva-permeable pouch of a packaging material enclosing the filling material, the filling material comprising or consisting of:

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from about 1 wt% to about 50 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising or consisting of:

(i) Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
(ii) a salt of Formula (I):

$$m^{2+}(A^{n-})_m \qquad \text{Formula I}$$

or a hydrate of said salt,
wherein

M^{2+} is selected from the group consisting of Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} and Fe^{2+},
A^{n-} is an anion selected from the group consisting of chloride, lactate, malate, succinate, citrate, ascorbate, tartrate, acetate, phosphate, sulphate, nitrate, gluconate, alginate, oxalate, aspartate, glycinate, picolinate, oxide, cysteinate, glutamate hydroxide, laurate, stearate, palmitate, undecylenate, gluceptate, glucerophosphate, glubionate, glucoheptonate, guanylate, inosinate, propionate, sorbate, salicylate, benzoate, erythorbate, formate, iodide, pangamate and any combination thereof,
n is 1 or 2,
m is 1 or 2, and

- (n x m)= -2,

said salt being present in an amount within the range of from about 0.05 wt% to about 5 wt%, based on the total weight of the filling material,
said salt having a water solubility equal to or above about 0.04 M and/or equal to or above 1 g/L, and

- optionally a tobacco material in an amount within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material.

[0037] It will be appreciated that in the salt of Formula I as described herein, n may have the value 1 and m may have the value 2. Alternatively, n may have the value 2 and m may have the value 1. Therefore, - (n x m)= -2.

[0038] The anion $A^{n'}$ of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, lactate, malate, citrate, ascorbate, acetate, sulphate, nitrate, gluconate, glutamate, guanylate, inosinate, propionate, sorbate, benzoate, formate, pangamate. For instance, M^{2+} may then be Ca^{2+}.

[0039] Further, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, lactate, citrate, ascorbate, acetate, sulphate, nitrate, propionate, benzoate, formate, pangamate. For instance, M^{2+} may then be Mg^{2+}.

[0040] Moreover, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, lactate, citrate, acetate, sulphate, nitrate, gluconate, benzoate, formate. For instance, M^{2+} may then be Mn^{2+}.

[0041] In an example, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, acetate, sulphate, nitrate, formate. In a further example, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, acetate, sulphate, nitrate, gluconate, propionate, formate. For instance, M^{2+} may then be Zn^{2+}.

[0042] In still a further example, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, acetate, sulphate, nitrate, gluconate, propionate, formate. In another example, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, lactate, sulphate, nitrate. For instance, M^{2+} may then be Fe^{2+}.

[0043] In still another example, the anion A^{n-} of the oral pouched nicotine product described herein may be selected from one or more of the following: chloride, lactate, malate, citrate, ascorbate, tartrate, acetate, gluconate, aspartate, glycinate.. For instance, M^{2+} may then be Ca^{2+}.

[0044] The pH adjusting agent of the oral pouched nicotine product as described herein allows the pH to be within the range of from about 7 to about 10. This pH may be achieved after manufacture of the product, such as immediately after manufacture of the product. Further, this pH is provided upon storage of the product such as upon storage as described herein. As described herein, achieving and/or maintaining a pH within the range of about 7 to about 10, such as from about 7 to about 9.5, such as from about 7 to about 9.2, such as from about 7 to about 9, such as from about 8 to about 9, is a significant advantage since it allows for good nicotine extraction and taste while not impacting oral mucous membranes negatively.

[0045] Storage of smokeless tobacco products comprising Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ as pH adjuster, leads to a decrease in the product pH. In contrast, the present inventors have found an increase in pH upon storage of oral pouched tobacco free nicotine products and oral pouched low tobacco nicotine products comprising Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ as pH adjuster. Surprisingly, it has been found that this increase in pH is counteracted by combining the Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ with a salt of Formula I as described herein.

[0046] While not wishing to be bound by any specific theory, it is believed that the salt of Formula I acts by preventing formation of hydroxide ions from water and the carbonate ions of the pH adjusting agent. Instead, it is believed that the salt of Formula I reacts with the carbonate ions of the pH adjusting agent to form a carbonate salt having low water solubility. For instance, when the salt of Formula I is $CaCl_2$ a carbonate salt of formula $CaCO_3$ may be formed. As a result, the pH of or in the oral pouched nicotine product into which the pH adjusting agent is incorporated increases less as compared to a corresponding product lacking the salt of Formula I.

[0047] The salt of Formula I may have a water solubility equal to or above about 0.04 M, such as above about 0.045 M, such as above about 0.05 M. Additionally or alternatively, the Formula I may have a water solubility equal to or above one or more of the following: about 0.045 M, such as equal to or above about 0.05 M, such as equal to or above about 0.06 M, such as equal to or above about 0.07 M, such as equal to or above about 0.8 M, such as equal to or above about 0.9 M, such as equal to or above about 1.0 M. Further, the salt of Formula I may have a water solubility equal to or less than about 10 M, such as less than about 5 M, such as less than about 3 M.

[0048] Moreover, the salt of Formula I may have a water solubility equal to or above about 1 g/L such as equal to or above about 2 g/L, such as equal to or above about 3 g/L, such as equal to or above about 4 g/L, such as equal to or above about 5 g/L, such as equal to or above about 10 g/L, such as equal to or above about 50 g/L, such as equal to

or above about 100 g/l, such as equal to or above about 150 g/L, such as equal to or above about 200 g/L, such as equal to or above about 250 g/L, such as equal to or above about 300 g/L, such as equal to or above about 350 g/L such as equal to or above about 400 g/L, such as equal to or above about 450 g/L, such as equal to or above about 500 g/L, such as equal to or above about 600 g/L, such as equal to or above about 700 g/L. Further, the salt of Formula I may have a water solubility equal to or less than about 1 kilogram/L, such as about 900 g/L, such as about 800 g/L. In this document, "g" stands for gram(s) and L stands for liter.

[0049] In this document, "M" stands for molar, i.e. mole per liter (i.e. mole/L or mol/L). Thus, the solubility may be measured in moles per liter of the solution. The solution may be the solution resulting from mixing such as dissolving the salt of Formula I with the water. Additionally or alternatively, the solution may be measured in g/L, i.e. gram(s) per liter of solution. The may be the solution resulting from dissolving the salt of Formula I with the water. Additionally or alternatively, the solution may be the solution to which the salt of Formula I is added.

[0050] The water solubility described herein such as the water solubility of the salt of Formula I described herein may be measured at a temperature from about 10 °C to about 40 °C, such as from about 20°C to about 25 °C. Further, the water solubility may be measured at atmospheric pressure such as at a pressure of about 101,325 Pa, i.e. 101,325 Pascal.

[0051] The oral pouched nicotine product may be free from tobacco, i.e. an oral pouched nicotine non-tobacco product.

[0052] Alternatively, the oral pouched nicotine product may comprise a low amount of tobacco material thereby providing an oral pouched low tobacco nicotine product. The amount of tobacco material of the oral pouched low tobacco nicotine product may be within the range of from about 0.1 % to about 10% by weight such as from about 0.1 % to about 5% by weight, such as from about 0.1 wt% to about 1 wt%, based on the total weight of the filling material. The presence of this small amount of tobacco will not impact the pH of the product to be substantially different from that exhibited by the oral pouched tobacco free products described herein.

[0053] The tobacco material may be provided in a form as described herein.

[0054] Further, the tobacco material may be a purified tobacco material, such as a bleached tobacco material or a tobacco extract.

[0055] The tobacco material described herein may comprise one, two or more particulate non-tobacco materials.

[0056] The amount of water of the filling material of the oral pouched nicotine product described herein may be present in an amount within the range of from about 0.5 wt% to about 12 wt% such as from about 0.5 wt% to about 5 wt%, such as from about 0.5 wt% to about 3 wt%, such as about 3 wt%, based on the total weight of the filling material. When the amount of water is within the range of from about 0.5 wt % to about 12 wt% or from about 0.5 wt% to about 3 wt% as described herein the oral pouched nicotine product may be considered dry, i.e. a dry oral pouched nicotine product.

[0057] Alternatively, the water content of the filling material of the oral pouched nicotine product described herein may be within the range of from about 20 wt% to about 50 wt%, such as from 20 wt% to 45 wt%, based on the total weight of the filling material. When the amount of water is within the range of from about 20 wt% to about 45 wt% as described herein the oral pouched nicotine product may be considered moist, i.e. a moist oral pouched nicotine product.

[0058] Surprisingly, it has been found that the pH adjusting agent described herein reduces, prevents and/or counteracts an increase in pH in an oral pouched nicotine product when it is stored. The oral pouched nicotine product may be dry or moist. The storage may be as described herein.

[0059] The salt of Formula I, or the hydrate of said salt, of the pH adjusting agent described herein may be present in an amount within the range of from about 0.05 wt% to about 10 wt%,such as from about 0.05 wt% to about 7 wt%, such as from about 0.05 wt% to about 5 wt%, such as from about 0.05 wt% to about 3 wt%, such as from about 0.05 wt% to about 2 wt%, such as from about 0.05 wt% to about 1 wt%, based on the total weight of the filling material. For example, the salt of Formula I or hydrate of the salt may be present in an amount within the range of from about 0.05 wt% to about 0.3 wt% or from about 0.1 wt% to about 0.3 wt%, based on the total weight of the filling material.

[0060] The Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ of the pH adjusting agent described herein may be present in an amount within the range of about 1 wt% to about 10 wt%, such as from about 1.5 wt% to about 4 wt% or from about 4 wt% to about 9 wt%, based on the total weight of the filling material of the oral pouched nicotine product.

[0061] The divalent metal ion M^{2+} of the salt of Formula I may be Ca^{2+} or Mg^{2+}. Alternatively, the divalent metal ion M^{2+} may be Mn^{2+}, Zn^{2+} or Fe^{2+}. For instance, the divalent metal ion M^{2+} of the salt of Formula may be Mn^{2+}. In a further example. the divalent metal ion M^{2+} of the salt of Formula may be Zn^{2+}. In still a further example, the divalent metal ion M^{2+} of the salt of Formula may be Fe^{2+}.

[0062] The salt of Formula I described herein may comprise or consist of $CaCl_2$ or a hydrate thereof. Additionally or alternatively, the salt of Formula I described herein may comprise or consist of $MgCl_2$ and/or $ZnCl_2$ or a hydrate of any of the aforementioned salts. Further, the salt of Formula I described herein may comprise or consist of $MnCl_2$ and/or $FeCl_2$ or a hydrate of the aforementioned salts.

[0063] The anion A^{n-} of the salt of Formula I described herein may be lactate. Thus, there is described a salt of Formula I as described herein which comprises or consists of calcium lactate and/or zinc lactate. Further, the salt of Formula I may comprise or consist of magnesium lactate and/or iron lactate. It will be appreciated that any of the aforementioned salts may be provided in the form of a hydrate.

[0064] The anion A^{n-} of the salt of Formula I described herein may be acetate. Thus, there is described a salt of Formula I as described herein which comprises or consists of calcium acetate and/or zinc acetate. Further, the salt of Formula I may comprise or consist of magnesium acetate and/or iron acetate. It will be appreciated that any of the aforementioned salts may be provided in the form of a hydrate.

[0065] In an example, the pH adjusting agent comprises or consists of Na_2CO_3 and $CaCl_2$. In a further example the pH adjusting agent comprises or consists of Na_2CO_3, $NaHCO_3$ and $CaCl_2$. In a further example, the pH adjusting agent comprises or consists of K_2CO_3 and $CaCl_2$. In yet a further example, the pH adjusting agent comprises or consists of $NaHCO_3$ and $CaCl_2$. In still a further example, the pH adjusting agent comprises or consists of $KHCO_3$ and $CaCl_2$.

[0066] In an example, the pH adjusting agent comprises or consists of (i) Na_2CO_3 and $NaHCO_3$ and (ii) $CaCl_2$ or a hydrate thereof.

[0067] The pH adjusting agent as described hereinmay be present in an amount from about 4 wt% to about 9 wt% based on the total weight of the filling material of the oral pouched nicotine product. Further, the amount of water may be within the range of from about 0.5 wt% to about 12 wt% or from about 0.5 wt% to about 3 wt%, based on the total weight of the filling material of the oral pouched nicotine product, and/or the amount of filling material may be within the range of from about 60 wt% to about 90 wt% or from about 30 wt% to about 85 wt%, based on the total weight of the filling material of the oral pouched nicotine product. Further, the non-particulate non-tobacco material may comprise or consist of maltitol and/or microcrystalline cellulose. In an example, the non-particulate non-tobacco material comprises or consists of microcrystalline cellulose and optionally maltitol.

[0068] The pH adjusting agent described herein may comprise or consist of (i) Na_2CO_3 and (ii) $CaCl_2$ or a hydrate thereof. The pH adjusting agent may be present in an amount from about 1.5 wt% to about 4 wt% based on the total weight of the filling material of the oral pouched nicotine product. Further, the amount of water may be within the range of from about 20 wt% to about 45 wt%, based on the total weight of the filling material of the oral pouched nicotine product, and/or the amount of filling material may be within the range of from about 30 wt% to about 90 wt% or from about 30 wt% to about 85 wt%, based on the total weight of the filling material of the oral pouched nicotine product. Further, the non-particulate non-tobacco material may comprise or consist of cellulose and/or microcrystalline cellulose.

[0069] The oral pouched nicotine product described herein may be free from sodium chloride, i.e. NaCl. Alternatively, it may comprise NaCl in an amount within the range of from about 0.1 wt% to about 5 wt% such as from about 0.1 wt% to about 3 wt%, based on the total weight of the filling material.

[0070] The oral pouched nicotine product described herein may further comprise $MgCO_3$. Additionally or alternatively, the oral pouched nicotine product described herein may comprise $CaCO_3$ and/or dolomite.

[0071] The oral pouched nicotine product described herein may comprise no further salt and/or no further pH adjuster.

[0072] The filling material of the oral pouched nicotine product described herein may comprise particulate non-tobacco material within the range of from about 30 wt% to about 90 wt%, such as from about 30 wt% to about 85 wt%, such as from about 30 wt% to about 80 wt%, such as from about 60 wt% to about 90 wt%, based on the total weight of the filling material. Further, the filling material described herein may be water-insoluble optionally further including water soluble filling material. Thus, at least part of the filling material of the oral pouched nicotine product described herein may be water-insoluble such as water-insoluble at room temperature and/or at atmospheric pressure.

[0073] The particulate non-tobacco material may be water-insoluble, water-soluble or a combination thereof.

[0074] The particulate non-tobacco material may comprise or consist of a sugar alcohol such as maltitol, and/or of cellulose such as microcrystalline cellulose and/or powdered cellulose. For instance, the particulate non-tobacco material may comprise maltitol and/or microcrystalline cellulose.

[0075] Additionally or alternatively, the filling material of the oral pouched nicotine product described herein may comprise one or more water-insoluble 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. In an example, the water-insoluble fibers may form part of the non-tobacco particulate material.

[0076] The filling material may comprise one, two or more nicotine sources.

[0077] The filling material of the oral pouched nicotine product as described herein may comprise within the range of from about 1.0 % to about 10 % by weight of the nicotine source, based on the total weight of the filling material.

[0078] The nicotine source may be a nicotine salt and/or nicotine base. The nicotine source such as nicotine base may be bound to an ion exchange resin, such as polacrilex, e.g. via a salt bridge. Alternatively or additionally, the ion exchange resin may function as a solid support for the nicotine source such as nicotine base.

[0079] Nicotine base, such as in the form of an oily liquid, may be synthetically produced or extracted from tobacco.

[0080] The nicotine source described herein may comprise or consist of one or more of the following: nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine polacrilex.

[0081] The nicotine source may be a nicotine salt such as a nicotine salt selected from the group consisting of nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine

sulphate, nicotine zinc chloride monohydrate and nicotine salicylate, and any combination thereof.

[0082] In particular, the filling material may comprise nicotine bitartrate and/or nicotine bitartrate dihydrate.

[0083] The amount of nicotine source such as nicotine salt and/or nicotine base per pouched product may be within the range from about 0.1 mg to about 20 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 12 mg, about 14 mg, about 16 mg, about 18 mg, or about 20 mg of nicotine.

[0084] The nicotine salt of the filling material in the oral pouched nicotine product as disclosed herein may be a nicotine salt present in solid form and/or dissolved form.

[0085] The nicotine source as disclosed herein may be adsorbed or non-adsorbed onto the particulate non-tobacco material as disclosed herein. It will be appreciated that the expression "adsorbed onto" means that the nicotine source adheres to an outer surface of the non-tobacco particulate material. When the nicotine source is adsorbed onto the non-tobacco particulate material it adheres to the outer surface of said non-tobacco particulate material without substantially penetrating into any void(s) of said non-tobacco particulate material.

[0086] Alternatively or additionally, the nicotine source as disclosed herein may be absorbed into and/or adsorbed onto the tobacco material described herein.

[0087] The filling material of the oral pouched nicotine product described herein may further comprise a flavouring agent. The filling material may comprise one, two or more flavouring agents. For example the flavouring agent may be a non-encapsulated agent. Additionally or alternatively, the flavouring agent may be encapsulated. The non- encapsulated flavouring agent and the encapsulated flavouring agent may be the same or different. As used herein, an encapsulated flavouring agent is a flavouring agent contained within a capsule. Accordingly, a non-encapsuled flavouring agent is not contained within a capsule.

[0088] The flavouring agent of the filling material in the oral pouched nicotine product as disclosed herein may be a hydrophobic flavouring agent.

[0089] The flavouring agent of the filling material of the oral pouched nicotine product described herein may be an oil, a liquid, a lyophilized material, a spray-dried material, or a mixture thereof. In an example, the flavouring agent(s) is/are an oil and/or a liquid.

[0090] The filling material of the oral pouched nicotine product described herein may comprise within the range of from about 0.5 % to about 3 % by weight of the flavouring agent, based on the total weight of the filling material.

[0091] The filling material of the oral pouched nicotine product described may comprise a humectant such as poly-propylene glycol.

[0092] In the oral pouched nicotine product as described herein, the particulate non-tobacco material, the nicotine source, the water, the pH adjusting agent, optionally the tobacco material, optionally the flavouring agent and optionally the humectant may be homogeneously mixed.

[0093] Anatabine is one of the minor alkaloids found in plants in the Solanaceae family, which inter alia includes the tobacco plant. The oral pouched nicotine non-tobacco product described herein may be free from tobacco, i.e. may contain no tobacco material, and may then consequently be free from anatabine. Alternatively, the oral pouched nicotine product described herein may contain a small amount of tobacco material, such as from about 0.1% to about 10% by weight as described herein, and may then not comprise any anatabine except for the anatabine present in said tobacco material.

[0094] The oral pouched nicotine product described herein may be free from glycerides such triglycerides. Alternatively, the oral pouched nicotine product described herein may comprise glycerides such as triglycerides.

[0095] The filling material of the oral pouched nicotine product as described herein may be manufactured using a method comprising the step(s) of:

- providing a mixture comprising a particulate non-tobacco material, a nicotine source such as a nicotine salt, and water, said mixture being provided by mixing the aforementioned components in any order,

wherein a pH adjusting agent as defined herein is added before, in and/or after any of the foregoing step(s), optionally a flavouring agent is added before, in and/or after any of the foregoing step(s), optionally a humectant is added before, in and/or after any of the foregoing step(s), and optionally a tobacco material is added in and/or after any of the foregoing step(s). The amount of the particulate non-tobacco material, the nicotine source, the water, the optional flavouring agent, the optional humectant and the optional tobacco material may be as described herein.

[0096] Further, the filling material of the oral pouched nicotine product as described herein may be manufactured using a method comprising the steps of:

- providing a powder comprising or consisting of a mixture comprising a particulate non-tobacco material, a nicotine source, a pH adjusting agent, water and optionally a tobacco material, and

- granulating said powder.

[0097] The method may further comprise a step of enclosing the filling material in a saliva-permeable pouch of a packaging material.

[0098] There is also provided a filling material and/or an oral pouched nicotine product obtained or obtainable by the method described herein.

[0099] The pH of the oral pouched nicotine product, such as the filling material of said oral pouched nicotine product, may be within the range of from about 7.0 to about 10.0, such as a pH within the range of from about 7 to about 9, such as from about 7 to about 9.5, such as from about 7 to about 9.2, such as from about 8 to about 9, such as about 8, such as about 8.3, such as about 8.5 or such as about 8.8, when it is dispersed in purified water. As described herein, these pH values are favourable for nicotine extraction and taste while not negatively affecting oral mucous membranes. The pH may be measured as described herein. Further, the oral pouched nicotine product may exhibit these pH values upon manufacture and/or also upon storage.

[0100] For example, the pH of the filling material may be measured by adding 100 milliliters (ml) of water such as distilled water to 5.0 grams of filling material to provide a mixture, followed by stirring of said mixture such as stirring at 100 rpm for about 5 minutes and then measuring the pH on at least part of said mixture. The pH of the filling material described herein may be measured at room temperature such as room temperature at atmospheric pressure. A pH meter may be used for the measurement. In this document, "rpm" stands for revolutions per minute. In this document, room temperature intends a temperature from about 20°C to about 25 °C, such as about 22°C. The atmospheric pressure may be a pressure of about 101,325 Pa, i.e. 101,325 Pascal.

[0101] Thus, there is provided an oral pouched nicotine product as described herein, wherein the pH of said product does not exceed about 10, does not exceed about 9.5 or does not exceed about 9 upon storage. Additionally or alternatively, the pH of the oral pouched nicotine product changes by no more than $\pm$ 0.5 pH units upon storage. The storage may take place at a relative humidity from about 60% to about 75%, at a temperature from about 22°C to about 30°C and/or for a time of about 15 weeks. In an example, the storage takes place at a relative humidity at about 75%, at a temperature at about 30°C and/or for a time of about 15 weeks. In a further example, the storage takes place at about 30°C and/or for a time of about 15 weeks.

[0102] The storage described herein may take place in a container such as a packaging and/or consumer container suitable for oral pouched nicotine products. Thus, the container described herein may be adapted for being conveniently carried in a consumer pocket or handbag, and/or may also be used for packaging any known type of snuff product such as oral pouched nicotine products as described herein. The container may be made of plastics and/or metal. Further, the container may have any desired shape or geometrical form. For example, the container may have the form of a cylinder. The container may comprise a top and a base defining an interior space. The base may comprise a base surface and surrounding walls extending from said base surface. The top may be in the form of a lid that is detachable from the base of the container, or in the form of a lid that is hinged or otherwise attached to the base of the container. For example, the lid may be attached by to the base by snap-fit. The container may be tamper resistant. In an example, the container may be as described in WO 2017/125405 which is incorporated herein in its entirety. In a further example, the container may be as shown in the Design Registration in Norway No. 085548.

[0103] Component (i) of the pH adjusting agent of the oral pouched nicotine product described herein may comprise or consist of one or more of the following: Na_2CO_3, K_2CO_3, $NaHCO_3$, $KHCO_3$. Further, the pH adjusting agent of the oral pouched nicotine product described herein may consist of:

(i) one or more of the following: Na_2CO_3, K_2CO_3, $NaHCO_3$, $KHCO_3$, and
(ii) a salt of Formula I as described herein.

[0104] For example, the pH adjusting agent of or in the oral pouched nicotine product as described herein may comprise or consist of:

(i) Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
(ii) a salt of Formula (I):

$$M2^{+}(A^{n-})_m \qquad \text{Formula I}$$

or a hydrate of said salt,
wherein

M^{2+} is selected from the group consisting of Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} and Fe^{2+},
A^{n-} is an anion selected from the group consisting of chloride, lactate, malate, succinate, citrate, ascorbate,

tartrate, acetate, phosphate, sulphate, nitrate, gluconate, alginate, oxalate, aspartate, glycinate, picolinate, oxide, cysteinate, glutamate hydroxide, laurate, stearate, palmitate, undecylenate, gluceptate, glucerophosphate, glubionate, glucoheptonate, guanylate, inosinate, propionate, sorbate, salicylate, benzoate, erythorbate, formate, iodide, pangamate and any combination thereof,
n is 1 or 2,
m is 1 or 2, and

- (n x m)= -2.

[0105] In an example, there is provided a pH adjusting agent as described herein in which:

M^{2+} is selected from the group consisting of Ca^{2+} and Mg^{2+}; and/or
$A^{n'}$ is selected from the group consisting of chloride, lactate, malate, citrate, ascorbate, tartrate, acetate, gluconate, aspartate and glycinate.

[0106] In an example, there is provided a pH adjusting agent as described herein in which:

M^{2+} is selected from the group consisting of Mn^{2+}, Zn^{2+} and Fe^{2+}, and/or
A^{n-} is selected from the group consisting of chloride, lactate, malate, citrate, ascorbate, tartrate, acetate, gluconate, aspartate and glycinate.

[0107] In one particular example, the pH adjusting agent described herein comprises or consists of (i) Na_2CO_3 and/or $NaHCO_3$, and (ii) $CaCl_2$. In further example, the pH adjusting agent may comprise or consist of (i) K_2CO_3 and/or $KHCO_3$, and (ii) $CaCl_2$. The $CaCl_2$ may be present in the form of a hydrate such as a monohydrate.

[0108] As described herein, an oral pouched nicotine product lacking the salt of Formula I increases its pH when it is stored. Unexpectedly, when the salt of Formula I is combined with Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, such as in amounts as described herein, this results in a pH adjusting agent that allows for:

(i) controlling, such as mitigating, reducing, preventing and/or counteracting an increase in pH of an oral pouched nicotine product when said product is stored,
(ii) preventing pH of an oral pouched nicotine product from exceeding a value of about 9, of about 9.2 or of about 9.5 when said product is stored, and/or
(iii) preventing pH of an oral pouched nicotine product from changing by more than ± 0.5 pH units, such as changing by more than ± 0.5 pH units from an initial pH value, when said product is stored. Thus, the pH adjusting agent allows for one or more of the following:

(i) controlling, such as mitigating, reducing, preventing and/or counteracting an increase in pH of an oral pouched nicotine product when said product is stored,
(ii) preventing pH of an oral pouched nicotine product from exceeding a value of about 9, of about 9.2 or of about 9.5 when said product is stored,
(iii) preventing pH of an oral pouched nicotine product from changing by more than ± 0.5 pH units, such as changing by more than ± 0.5 pH units from an initial pH value, when said product is stored.

[0109] It will be appreciated that the expression "± 0.5 pH units" used herein may intend + 0.5 pH units and/or - 0.5 pH units.

[0110] Thus, there is provided a use of a salt of Formula I, or a hydrate of said salt, as described herein for controlling pH in or of an oral pouched nicotine product comprising a filling material, said filling material comprising said salt of Formula I, or a hydrate thereof, and

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from 1 wt% to 45 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising or consisting of Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
- optionally a tobacco material within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material,

when said product is stored, such as stored
at a relative humidity from 60% to 75%,

at a temperature from 22°C to 30 °C, and/or
for a time of 15 weeks.

[0111] The salt of Formula I, or a hydrate thereof, may be mixed with the other components of the filling material. For instance, the salt of Formula I, or a hydrate thereof, may be substantially homogenously mixed with the other components of the filling material.

[0112] It will be appreciated that the amount of the filling material components may be as described in this document. For instance, the salt of Formula I such as $CaCl_2$, Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ may be present in amounts as described herein. In an example, the salt of Formula I such as CaCl2, Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ may be present in an amount such as a total amount from 1 wt% to 15 wt%, such as from 1 wt% to 10 wt%, such as from 1 wt% to 9 wt%, such as from 1 to 7 wt% or such as from 1 wt% to 5 wt%, based on the total weight of the filling material of said oral pouched nicotine product.

[0113] The controlling may comprise or consist of:

(i) mitigating an increase in pH in or of said product when said product is stored,
(ii) preventing pH in or of said product from exceeding a value of about 9, of about 9.2 or of about 9.5 when said product is stored, and/or
(iii) preventing pH in or of said product from changing by more than ± 0.5 pH units, such as changing by more than ± 0.5 pH units as compared to pH of a corresponding freshly prepared product, when said product is stored. Thus, the controlling may comprise or consist of one or more of the following:

(i) mitigating an increase in pH in or of said product when said product is stored,
(ii) preventing pH in or of said product from exceeding a value of about 9, of about 9.2 or of about 9.5 when said product is stored,
(iii) preventing pH in or of said product from changing by more than ± 0.5 pH units, such as changing by more than ± 0.5 pH units as compared to pH of a corresponding freshly prepared product, when said product is stored.

[0114] The storage described herein may take place at a relative humidity from about 60% to about 75%, at a temperature from about 22°C to about 30°C and/or for a time of about 15 weeks. In an example, the storage takes place at a relative humidity at about 75%, at a temperature at about 30°C and/or for a time of about 15 weeks. In a further example, the storage takes place at about 30°C and/or for a time of about 15 weeks.

[0115] The present disclosure also provides a method for controlling pH in or of an oral pouched nicotine product, such as an oral pouched nicotine product as described herein, when said product is stored. The controlling may be as described herein. The method involves use of a pH adjusting agent as described herein. The method may comprise or consist of preparing an oral pouched nicotine product as described herein followed by storage of said product. The storage may be as described herein.

[0116] The controlling of pH as described herein may impart an improved storage stability such as improved storage stability of an oral pouched nicotine product as described herein. In particular, the storage stability may be improved with respect to a corresponding oral pouched nicotine product lacking the salt of Formula I.

[0117] It will be appreciated that the oral pouched nicotine product described herein may be considered a portion packed oral nicotine product. The filling material may be in the form of a particles, granules, beads, a powder such as a dry powder or a moist powder, a dry mixture or a moist mixture. Further, the present disclosure is also directed to the filling material as described herein, i.e. the filling material as such excluding any packaging such as a pouch.

EXAMPLES

Example 1: Substantially dry oral pouched tobacco free nicotine product

[0118] Five granulates were prepared by mixing anhydrous calcium chloride (supplied by Merck GmbH, Germany), nicotine bitartrate dihydrate (supplied by Siegfried AG, Switzerland), sodium bicarbonate (supplied by TATA Chemicals, UK) and sodium carbonate (supplied by Novacarb, France) with fillers such as sugar alcohol and cellulose fiber according to Table 1B below.

Table 1A

Sample	Calcium chloride (w/w%)	Nicotine bitartrate dihydrate (w/w%)	Sodium bicarbonate (w/w%)	Sodium carbonate (w/w%)	Fillers (w/w%)	Start moisture (w/w%)
1	0	2.51	2.33	1.91	93.25	1.08
2	0.1	2.51	2.33	1.91	93.15	1.02
3	1	2.51	2.33	1.91	92.25	1.38
4	5	2.51	2.33	1.91	88.25	2.00
5	10	2.51	2.33	1.91	83.25	3.86

[0119] The moisture content in Table 1A was determined as described herein using the method in 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).

[0120] The granulates were packed into portion pouches of 0.4 g each using a water permeable nonwoven pouch material. The pouches were packed into plastic cans suitable for containment of oral pouches. The plastic cans were as described in WO 2017/125405. The pH was analysed for the fresh samples before storage, using the herein described method. The plastic cans were thereafter transferred to a climate cabinet (VC0100, Vötsch Industrietechnik) for storage. The cabinet conditions were set at 35°C and 75 % RH. Storage was done for 15 weeks. After 2, 4, 6, 8, 10 and 15 weeks cans from each sample were taken out of the climate cabinet and the pH of the pouches was analyzed, using the herein defined method. In this document, "g" stands for gram(s) and "RH" stands for relative humidity.

[0121] The results are shown in Figure 1 and Table 1B. It can be seen that the reference without calcium chloride (Sample 1) increased by more than 1 pH unit after storage for 15 weeks. Thus, the pH of the oral pouched tobacco free nicotine product lacking $CaCl_2$ increased upon storage. In contrast, the pH of samples 2-5, which contained a combination of calcium chloride, sodium bicarbonate and sodium carbonate, increased by 0.45 pH units or less upon storage. Further, after storage the pH of samples 2-5 was from 7.40 to 8.61. Thus, pH increased less in the presence of a salt such as $CaCl_2$.

Table 1B

Sample	pH at 0 weeks	pH at 15 weeks	pH change at 15 weeks
1	8.54	9.58	1.04
2	8.57	8.52	-0.05
3	8.16	8.61	0.45
4	7.78	7.58	-0.20
5	7.86	7.44	-0.42

Example 2: Snus products

[0122] This is a comparative example in which it is shown how the pH of snus changes upon storage.

[0123] Two batches of snus (GR One and General One) were prepared in a standard snus production procedure using production scale equipment and the composition disclosed in Table 2. Tobacco, fibre and water were mixed in a blender. The blend was heated to 100°C and the temperature kept between 85-100 °C for 4.5 hours. Before cooling sodium chloride, sodium carbonate, propylene glycol and additional water was added and mixed into the snus blend. After cooling a final addition of flavour and additional sodium chloride were added and mixed into the snus blend. The snus was packed into water permeable nonwoven pouch material and the pouches packed into plastic cans suitable for containment of oral pouches. The plastic cans were as shown in the Design Registration in Norway No. 085548.

[0124] The pH was analyzed for the fresh samples before storage, using the herein described method. The plastic cans were thereafter transferred to a climate cabinet for storage. The cabinet conditions were set at 22 °C and 60 % RH. Storage was done for 17 weeks. After 1, 3, 5, 10 and 17 weeks cans from each sample were taken out of the climate cabinet and the pH of the pouches was analyzed, using the herein defined method.

[0125] The results are shown in Figure 2. It can be seen that in both snus samples the pH-value follows a typical pH-

development for snus during storage. This means that the pH decreased steadily. After storage for 17 weeks the pH decreased approximately by 0.6 pH-units, as compared to the initial value. Thus, the pH of tobacco containing snus decreases upon storage.

Table 2

Sample	Tobacco flour (w/w%)	Water (w/w%)	Sodium chloride (w/w%)	Sodium carbonate (w/w%)	Fibre, propylene glycol, flavour, pouch paper (w/w%)
GR One	44.7	39.1	3.4	3.2	9.6
General One	44.7	38.8	3.4	3.2	9.9

Example 3: Moist oral tobacco free nicotine product

[0126] Two batches (Ang-124 and Ang-125) of a moist oral nicotine product were prepared in lab scale (500 g per batch) according to the composition in Table 3A. Dry ingredients (nicotine bitartrate, sodium carbonate, calcium chloride (only in Ang-124), cellulose, sodium chloride and sweetener were mixed in a lab mixer (Kenwood) to a homogenous powder blend. Water, glycerol and vegetable oil were added followed by continued mixing. The water was present in an amount of about 30-40 wt% based on the total amount of the composition.

[0127] Thereafter flavour and sweetener were added and the blend mixed to a final oral nicotine blend. The pH was analyzed for the fresh samples before storage, using the herein described method.

Table 3A

Sample	**Nicotine bitartrate (w/w%)**	**Sodium carbonate (w/w%)**	**Calcium chloride (w/w%)**	**Water, glycerol, vegetable oil (w/w%)**	**Cellulose, sodium chloride, flavour, sweetener (w/w%)**
Ang-124	4.6	2.3	1.5	46.6	45.0
Ang-125	4.6	2.5	0	46.7	46.2

[0128] The two samples of oral nicotine blend were distributed in plastic cans suitable for oral pouched nicotine products. The plastic cans were thereafter sealed with a side label and transferred to a climate cabinet for storage. The plastic cans were as shown in the Design Registration in Norway No. 085548. The cabinet conditions were set at 22 °C and 60 % RH. Storage was done for 15 weeks. After 2, 4, 8, 10 and 15 weeks cans from each sample were taken out of the climate cabinet and the pH of the pouches was analyzed, using the herein defined method.

[0129] The results are shown in Figure 3 and Table 3B. It can be seen that the pH of the reference without calcium chloride (Ang-125) increased by 0.86 pH unit upon storage for 15 weeks. In contrast, the pH of the sample comprising calcium chloride (Ang-124) increased only by 0.40 pH units upon storage. The pH after storage for the sample Ang-124 was 9.04. Thus, pH increased less in the presence of a salt such as $CaCl_2$.

Table 3B

Sample	**pH at 0 weeks**	**pH at 15 weeks**	**pH change at 15 weeks**
Ang-124	8.63	9.04	0.4
Ang-125	8.81	9.67	0.86

Method for measurement of pH

[0130] The pH of the filling material of the above-mentioned examples was measured by adding 100 ml of distilled water to 5.0 gram of filling material, in a 125 ml beaker, 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

[0131] (according to the manufacturer's instructions) pH meter. For correctness of readings, the sample solutions were analyzed within one hour. In this document, "rpm" stands for revolutions per minute. In this document, room temperature intends a temperature from about 20 °C to about 25 °C, such as about 22 °C.

Claims

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

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from 1 wt% to 50 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising:

(i) Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
(ii) a salt of Formula (I):

$$m^{2+}(A^{n-})_m \qquad \text{Formula I}$$

or a hydrate of said salt,
wherein

M^{2+} is selected from the group consisting of Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} and Fe^{2+},
A^{n-} is an anion selected from the group consisting of chloride, lactate, malate, succinate, citrate, ascorbate, tartrate, acetate, phosphate, sulphate, nitrate, gluconate, alginate, oxalate, aspartate, glycinate, picolinate, oxide cysteinate, glutamate, hydroxide, laurate, stearate, palmitate, undecylenate, gluceptate, glucerophosphate, glubionate, glucoheptonate, guanylate, inosinate, propionate, sorbate, salicylate, benzoate, erythorbate, formate, iodide, pangamate and any combination thereof,
n is 1 or 2,
m is 1 or 2, and

- $(n \times m) = -2$,

said salt being present in an amount within the range of from 0.05 wt% to 5 wt%, based on the total weight of the filling material,
said salt having a water solubility equal to or above 0.04 M and/or equal to or above 1 g/L, and

- optionally a tobacco material in an amount within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material;

wherein the pH of said filling material of said oral pouched nicotine product does not exceed 9.5 upon storage and/or changes by no more than $\pm$ 0.5 pH units upon storage,
such as storage taking place
at a relative humidity from 60% to 75%,
at a temperature from 22°C to 30°C, and/or
for a time of 15 weeks.

2. An oral pouched nicotine product according to claim 1 wherein said salt has a water solubility equal to or above 0.045 M, such as equal to or above 0.05 M, such as equal to or above 0.06 M, such as equal to or above 0.07 M, such as equal to or above 0.8 M, such as equal to or above 0.9 M, such as equal to or above 1.0 M.

3. An oral pouched nicotine product according to claim 1 or 2, wherein said salt has a water solubility equal to or above 2 g/L, such as equal to or above 3 g/L, such as equal to or above 4 g/L, such as equal to or above 5 g/L, such as equal to or above 10 g/L, such as equal to or above 50 g/L, such as equal to or above 100 g/l, such as equal to or above 150 g/L, such as equal to or above 200 g/L, such as equal to or above 250 g/L, such as equal to or above 300 g/L, such as equal to or above 350 g/L such as equal to or above 400 g/L, such as equal to or above 450 g/L, such as equal to or above 500 g/L, such as equal to or above 600 g/L, such as equal to or above 700 g/L.

4. An oral pouched nicotine product according to any one of claims 1-3, wherein said water solubility is measured at a temperature from 10°C to 40 °C, such as from 20°C to 25°C.

5. An oral pouched nicotine product according to any one of the preceding claims, wherein A^{n-} is an anion selected

from one or more of the following: chloride, lactate, malate, citrate, ascorbate, acetate, sulphate, nitrate, gluconate, glutamate, guanylate, inosinate, propionate, sorbate, benzoate, formate, pangamate; such as an anion selected from one or more of the following: chloride, lactate, citrate, ascorbate, acetate, sulphate, nitrate, propionate, benzoate, formate, pangamate; such as an anion selected from one or more of the following: chloride, lactate, citrate, acetate, sulphate, nitrate, gluconate, benzoate, formate; such as an anion selected from one or more of the following: chloride, acetate, sulphate, nitrate, formate; such as an anion selected from one or more of the following: chloride, acetate, sulphate, nitrate, gluconate, propionate, formate; such as an anion selected from one or more of the following: chloride, lactate, sulphate, nitrate; such as an anion selected from one or more of the following: chloride, lactate, malate, citrate, ascorbate, tartrate, acetate, gluconate, aspartate, glycinate.

6. An oral pouched nicotine product according to any one of the preceding claims, wherein the filling material does not comprise a tobacco material or wherein tobacco material is present in an amount within the range of from 0.1 wt% to 10 wt%, such as from 0.1 wt% to 5 wt%, such as from 0.1 wt% to 1 wt%, based on the total weight of the filling material.

7. An oral pouched nicotine product according to any one of the preceding claims, wherein the amount of water is within the range of from 0.5 wt% to 12 wt%, such as from 0.5 wt% to 5 wt%, such as 3 wt%, based on the total weight of the filling material or wherein the amount of water is within the range of from 20 wt% to 50 wt%, such as from 20 wt% to 45 wt%, based on the total weight of the filling material.

8. An oral pouched nicotine product according to any one of the preceding claims, wherein the salt of Formula (I), or hydrate of said salt, is present in an amount within the range of from 0.05 wt% to 5 wt%, such as from 0.1 wt% to 5 wt%, such as from 0.1 wt% to 3 wt%, such as from 0.1 wt% to 2 wt%, such as from 0.1 wt% to 1 wt%, based on the total weight of the filling material, such as wherein the salt of Formula (I), or a hydrate of said salt, is present in an amount within the range of from 0.05 wt% to 0.3 wt%, based on the total weight of the filling material.

9. An oral pouched nicotine product according to any one of the preceding claims, wherein the Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$ of the pH adjusting agent is/are present in an amount within the range of from 1 wt% to 10 wt%, such as from 1.5 wt% to 4 wt% or from 4 wt% to 9 wt%, based on the total weight of the filling material.

10. An oral pouched nicotine product according to any one of the preceding claims, wherein M^{2+} is Ca^{2+} or Mg^{2+}.

11. An oral pouched nicotine product according to any one of claims 1-9, wherein M^{2+} is Mn^{2+}, Zn^{2+} or Fe^{2+}.

12. An oral pouched nicotine product according to any one of claims 1-10, wherein the salt of Formula (I) comprises or consists of $CaCl_2$ or a hydrate thereof.

13. An oral pouched nicotine product according to any one of the preceding claims, wherein the filling material further comprises NaCl, such as NaCl in an amount within the range of from 0.1 wt% to 5 wt% such as from 0.1 wt% to 3 wt%, based on the total weight of the filling material.

14. An oral pouched nicotine product according to any one of the preceding claims, wherein the filling material further comprises $MgCO_3$.

15. An oral pouched nicotine product according to any one of the preceding claims, wherein said product comprises no further salt and/or no further pH adjuster.

16. An oral pouched nicotine product according to any one of the preceding claims, wherein said filling material of said oral pouched nicotine product has a pH from 7 to 10, such as from 8 to 9, such as 8, 8.3, 8.5 or 8.8, when it is dispersed in purified water.

17. An oral pouched nicotine product according to any one of the preceding claims, wherein at least part of the filling material is water-insoluble.

18. An oral pouched nicotine product according to any one of the preceding claims, wherein the particulate non-tobacco material comprises microcrystalline cellulose and optionally maltitol.

19. An oral pouched nicotine product according to any one of the preceding claims, wherein the filling material comprises

one or more water-insoluble 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.

20. 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 hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine polacrilex, such as wherein the nicotine source is nicotine bitartrate and/or nicotine bitartrate dihydrate.

21. An oral pouched nicotine product according to any one of the preceding claims, wherein the pH of said filling material of said oral pouched nicotine product does not exceed 9.5 upon storage and/or changes by no more than ± 0.5 pH units upon storage taking place

at a relative humidity from 60% to 75%,
at a temperature from 22°C to 30°C, and/or
for a time of 15 weeks.

22. Use of a salt of Formula (I), or a hydrate of said salt, as defined in any one of the preceding claims for controlling pH in an oral pouched nicotine product comprising a filling material, said filling material comprising said salt of Formula (I), or a hydrate thereof, and :

- a particulate non-tobacco material,
- a nicotine source,
- water in an amount within the range of from 1 wt% to 50 wt% such as from 1 wt% to 45 wt% based on the total weight of the filling material, and
- a pH adjusting agent comprising or consisting of Na_2CO_3, K_2CO_3, $NaHCO_3$ and/or $KHCO_3$, and
- optionally a tobacco material within the range of from 0.05 wt% to 10 wt % based on the total weight of the filling material,

when said product is stored, such as stored
at a relative humidity from 60% to 75%,
at a temperature from 22°C to 30 °C, and/or
for a time of 15 weeks.

23. Use according to claim 22, wherein said controlling comprises or consists of mitigating an increase in pH in said product, preventing pH in said product from exceeding a value of 9.5, and/or preventing pH in said product from changing by more than ± 0.5 pH units.

24. Use according to claim 22 or 23, wherein the salt of Formula (I), is as defined in any one of claims 1-5.

25. Use according to any one of claims 22-24 wherein the salt of Formula (I), Na_2CO_3, $NaHCO_3$, K_2CO_3 and/or $KHCO_3$ is/are present in a total amount from 1 wt% to 15 wt%, such as from 1 wt% to 10 wt%, such as from 1 wt% to 9 wt%, such as from 1 to 7 wt% or such as from 1 wt% to 5 wt%, based on the total weight of the filling material.

Patentansprüche

1. Orales Nikotinbeutelerzeugnis, umfassend ein Füllmaterial und einen speicheldurchlässigen Beutel aus einem Verpackungsmaterial, das das Füllmaterial umschließt, das Füllmaterial umfassend:

- ein teilchenförmiges Nicht-Tabakmaterial,
- eine Nikotinquelle,
- Wasser in einer Menge innerhalb des Bereichs von 1 Gew.-% bis 50 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, und
- ein pH-Wert-Einstellmittel, umfassend:

(i) Na_2CO_3, K_2CO_3, $NaHCO_3$ und/oder $KHCO_3$, und
(ii) ein Salz der Formel (I):

$M^{2+}(A^{n-})_m$ Formel I

oder ein Hydrat des Salzes,
wobei

M^{2+} aus der Gruppe ausgewählt ist, bestehend aus Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} und Fe^{2+}, A^{n-} ein Anion ist, das aus der Gruppe ausgewählt ist, bestehend aus Chlorid, Lactat, Malat, Succinat, Citrat, Ascorbat, Tartrat, Acetat, Phosphat, Sulfat, Nitrat, Gluconat, Alginat, Oxalat, Aspartat, Glycinat, Picolinat, Oxidcysteinat, Glutamat, Hydroxid, Laurat, Stearat, Palmitat, Undecylenat, Gluceptat, Glucerophosphat, Glubionat, Glucoheptonat, Guanylat, Inosinat, Propionat, Sorbat, Salicylat, Benzoat, Erythorbat, Formiat, Iodid, Pangamat und einer beliebigen Kombination davon,
n 1 oder 2 ist,
m 1 oder 2 ist, und

- $(n \times m) = -2$,

das Wasser in einer Menge innerhalb des Bereichs von 0,05 Gew.-% bis 5 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist,
wobei das Salz eine Wasserlöslichkeit gleich oder über 0,04 M und/oder gleich oder über als 1 g/L aufweist, und

- optional ein Tabakmaterial in einer Menge innerhalb des Bereichs von 0,05 Gew.-% bis 10 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials;

wobei der pH-Wert des Füllmaterials des oralen Nikotinbeutelerzeugnisses bei einer Lagerung 9,5 nicht überschreitet und/oder sich bei der Lagerung um nicht mehr als ± 0,5 pH-Wert-Einheiten ändert,
wie etwa die Lagerung, die stattfindet
bei einer relativen Luftfeuchtigkeit von 60 % bis 75 %,
bei einer Temperatur von 22°C bis 30 °C und/oder
für eine Zeit von 15 Wochen.

2. Orales Nikotinbeutelerzeugnis nach Anspruch 1, wobei das Salz eine Wasserlöslichkeit gleich oder über 0,045 M, wie etwa gleich oder über 0,05 M, wie etwa gleich oder über 0,06 M, wie etwa gleich oder über 0,07 M, wie etwa gleich oder über 0,8 M, wie etwa gleich oder über 0,9 M, wie etwa gleich oder über 1,0 M aufweist.

3. Orales Nikotinbeutelerzeugnis nach Anspruch 1 oder 2, wobei das Salz eine Wasserlöslichkeit gleich oder über 2 g/l, wie etwa gleich oder über 3 g/l, wie etwa gleich oder über 4 g/l, wie etwa gleich oder über 5 g/l, wie etwa gleich oder über 10 g/l, wie etwa gleich oder über 50 g/l, wie etwa gleich oder über 100 g/l, wie etwa gleich oder über 150 g/l, wie etwa gleich oder über 200 g/l, wie etwa gleich oder über 250 g/l, wie etwa gleich oder über 300 g/l, wie etwa gleich oder über 350 g/l, wie etwa gleich oder über 400 g/l, wie etwa gleich oder über 450 g/l, wie etwa gleich oder über 500 g/l, wie etwa gleich oder über 600 g/l, wie etwa gleich oder über 700 g/l aufweist.

4. Orales Nikotinbeutelerzeugnis nach einem der Ansprüche 1 bis 3, wobei die Wasserlöslichkeit bei einer Temperatur von 10°C bis 40 °C, wie etwa von 20°C bis 25 °C, gemessen wird.

5. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei A^{n-} ein Anion ist, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Lactat, Malat, Citrat, Ascorbat, Acetat, Sulfat, Nitrat, Gluconat, Glutamat, Guanylat, Inosinat, Propionat, Sorbat, Benzoat, Formiat, Pangamat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Lactat, Citrat, Ascorbat, Acetat, Sulfat, Nitrat, Propionat, Benzoat, Formiat, Pangamat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Lactat, Citrat, Acetat, Sulfat, Nitrat, Gluconat, Benzoat, Formiat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Acetat, Sulfat, Nitrat, Formiat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Acetat, Sulfat, Nitrat, Gluconat, Propionat, Formiat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Lactat, Sulfat, Nitrat; wie etwa ein Anion, das aus einem oder mehreren der Folgenden ausgewählt ist: Chlorid, Lactat, Malat, Citrat, Ascorbat, Tartrat, Acetat, Gluconat, Aspartat, Glycinat.

6. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Füllmaterial kein Tabakmaterial

umfasst oder wobei Tabakmaterial in einer Menge innerhalb des Bereichs von 0,1 Gew.-% bis 10 Gew.-%, wie etwa von 0,1 Gew.-% bis 5 Gew.-%, wie etwa von 0,1 Gew.-% bis 1 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist.

7. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei die Menge an Wasser innerhalb des Bereichs von 0,5 Gew.-% bis 12 Gew.-%, wie etwa von 0,5 Gew.-% bis 5 Gew.-%, wie etwa 3 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, liegt, oder wobei die Menge an Wasser innerhalb des Bereichs von 20 Gew.-% bis 50 Gew.-%, wie etwa 20 Gew.-% bis 45 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, liegt.

8. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Salz der Formel (I) oder das Hydrat des Salzes in einer Menge innerhalb des Bereichs von 0,05 Gew.-% bis 5 Gew.-%, wie etwa von 0,1 Gew.-% bis 5 Gew.-%, wie etwa von 0,1 Gew.-% bis 3 Gew.-%, wie etwa von 0,1 Gew.-% bis 2 Gew.-%, wie etwa von 0,1 Gew.-% bis 1 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist, wie etwa wobei das Salz der Formel (I) oder ein Hydrat des Salzes in einer Menge innerhalb des Bereichs von 0,05 Gew.-% bis 0,3 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist.

9. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Na_2CO_3, K_2CO_3, $NaHCO_3$ und/oder $KHCO_3$ des pH-Wert-Einstellmittels in einer Menge innerhalb des Bereichs von 1 Gew.-% bis 10 Gew.-%, wie etwa von 1,5 Gew.-% bis 4 Gew.-% oder von 4 Gew.-% bis 9 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist/sind.

10. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei M^{2+} Ca^{2+} oder Mg^{2+} ist.

11. Orales Nikotinbeutelerzeugnis nach einem der Ansprüche 1 bis 9, wobei M^{2+} Mn^{2+}, Zn^{2+} oder Fe^{2+} ist.

12. Orales Nikotinbeutelerzeugnis nach einem der Ansprüche 1 bis 10, wobei das Salz der Formel (I) $CaCl_2$ oder ein Hydrat davon umfasst oder daraus besteht.

13. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Füllmaterial ferner NaCl, wie etwa NaCl in einer Menge innerhalb des Bereichs von 0,1 Gew.-% bis 5 Gew.-%, wie etwa von 0,1 Gew.-% bis 3 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, umfasst.

14. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Füllmaterial ferner MgCOa umfasst.

15. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Erzeugnis kein weiteres Salz und/oder keinen weiteren pH-Wert-Einsteller umfasst.

16. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Füllmaterial des oralen Nikotinbeutelerzeugnisses einen pH-Wert von 7 bis 10, wie etwa von 8 bis 9, wie etwa 8, 8,3, 8,5 oder 8,8, wenn es in gereinigtem Wasser dispergiert wird, aufweist.

17. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei mindestens ein Teil des Füllmaterials wasserunlöslich ist.

18. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das teilchenförmige Nicht-Tabakmaterial mikrokristalline Cellulose und optional Maltit umfasst.

19. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei das Füllmaterial eine oder mehrere wasserunlösliche Fasern umfasst, die aus der Gruppe ausgewählt sind, bestehend aus Maisfasern, Haferfasern, Tomatenfasern, Gerstenfasern, Roggenfasern, Zuckerrübenfasern, Buchweizenfasern, Weizenfasern, Erbsenfasern, Kartoffelfasern, Apfelfasern, Kakaofasern, Bambusfasern, Zitrusfasern und einer beliebigen Kombination davon.

20. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei die Nikotinquelle eines oder mehrere der Folgenden ist: Nikotinhydrochlorid, Nikotindihydrochlorid, Nikotinmonotartrat, Nikotinbitartrat, Nikotinbitartratdihydrat, Nikotinsulfat, Nikotinzinkchloridmonohydrat, Nikotinsalicylat, Nikotinpolacrilex, wie etwa wobei die Nikotin-

quelle Nikotinbitartrat und/oder Nikotinbitartratdihydrat ist.

21. Orales Nikotinbeutelerzeugnis nach einem der vorstehenden Ansprüche, wobei der pH-Wert des Füllmaterials des oralen Nikotinbeutelerzeugnisses bei der Lagerung 9,5 nicht überschreitet und/oder sich bei der Lagerung um nicht mehr als ± 0,5 pH-Wert-Einheiten ändert, wenn die Lagerung stattfindet

bei einer relativen Luftfeuchtigkeit von 60 % bis 75 %,
bei einer Temperatur von 22°C bis 30 °C und/oder
für eine Zeit von 15 Wochen.

22. Verwendung eines Salzes der Formel (I) oder eines Hydrats des Salzes, wie in einem der vorstehenden Ansprüche definiert, zum Steuern des pH-Werts in einem oralen Nikotinbeutelerzeugnis, umfassend ein Füllmaterial, das Füllmaterial umfassend das Salz der Formel (I) oder ein Hydrat davon, und:

- ein teilchenförmiges Nicht-Tabakmaterial,
- eine Nikotinquelle,
- Wasser in einer Menge innerhalb des Bereichs von 1 Gew.-% bis 50 Gew.-%, wie etwa von 1 Gew.-% bis 45 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, und
- ein pH-Wert-Einstellmittel, umfassend oder bestehend aus Na_2CO_3, K_2CO_3, $NaHCO_3$ und/oder $KHCO_3$, und
- optional ein Tabakmaterial innerhalb des Bereichs von 0,05 Gew.-% bis 10 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials,

wenn das Erzeugnis gelagert wird, wie etwa gelagert
bei einer relativen Luftfeuchtigkeit von 60 % bis 75 %,
bei einer Temperatur von 22°C bis 30 °C und/oder
für eine Zeit von 15 Wochen.

23. Verwendung nach Anspruch 22, wobei das Steuern ein Mildern eines Anstiegs des pH-Werts in dem Erzeugnis umfasst oder daraus besteht, was verhindert, dass der pH-Wert in dem Erzeugnis einen Wert von 9,5 überschreitet, und/oder verhindert, dass sich der pH-Wert in dem Erzeugnis um mehr als ± 0,5 pH-Wert-Einheiten ändert.

24. Verwendung nach Anspruch 22 oder 23, wobei das Salz der Formel (I) wie in einem der Ansprüche 1 bis 5 definiert ist.

25. Verwendung nach einem der Ansprüche 22 bis 24, wobei das Salz der Formel (I), Na_2CO_3, $NaHCO_3$, K_2CO_3 und/oder $KHCO_3$ in einer Gesamtmenge von 1 Gew.-% bis 15 Gew.-%, wie etwa von 1 Gew.-% bis 10 Gew.-%, wie etwa von 1 Gew.-% bis 9 Gew.-%, wie etwa von 1 bis 7 Gew.-% oder wie etwa von 1 Gew.-% bis 5 Gew.-%, basierend auf dem Gesamtgewicht des Füllmaterials, vorhanden ist/sind.

Revendications

1. Produit oral à base de nicotine en sachet comprenant un matériau de remplissage et un sachet perméable à la salive d'un matériau d'emballage renfermant le matériau de remplissage, le matériau de remplissage comprenant :

- un matériau particulaire sans tabac,
- une source de nicotine,
- de l'eau en une quantité comprise dans la plage de 1 % en poids à 50 % en poids sur la base du poids total du matériau de remplissage, et
- un agent d'ajustement du pH comprenant :

(i) Na_2CO_3, K_2CO_3, $NaHCO_3$ et/ou $KHCO_3$, et
(ii) un sel de formule (I) :

$$m^{2+}(A^{n-})_m \qquad \text{Formule I}$$

ou un hydrate dudit sel,
dans lequel

M^{2+} est choisi dans le groupe constitué de Ca^{2+}, Mg^{2+}, Mn^{2+}, Zn^{2+} et Fe^{2+}, A^{n-} est un anion choisi dans le groupe constitué de chlorure, lactate, malate, succinate, citrate, ascorbate, tartrate, acétate, phosphate, sulfate, nitrate, gluconate, alginate, oxalate, aspartate, glycinate, picolinate, oxyde, cystéinate, glutamate, hydroxyde, laurate, stéarate, palmitate, undécylénate, gluceptate, glucérophosphate, glubionate, glucohéptonate, guanylate, inosinate, propionate, sorbate, salicylate, benzoate, érythorbate, formiate, iodure, pangamate et leur combinaison quelconque,
n est 1 ou 2,
m est 1 ou 2, et

- $(n \times m) = -2$,

ledit sel étant présent en une quantité dans la plage de 0,05 % en poids à 5 % en poids, sur la base du poids total du matériau de remplissage,
ledit sel ayant une solubilité dans l'eau égale ou supérieure à 0,04 M et/ou égale ou supérieure à 1 g/L, et

- éventuellement un matériau de tabac en une quantité comprise dans la plage de 0,05 % en poids à 10 % en poids sur la base du poids total du matériau de remplissage ; dans lequel le pH dudit matériau de remplissage dudit produit oral à base de nicotine en sachet ne dépasse pas 9,5 lors du stockage et/ou ne varie pas de plus de $\pm$ 0,5 unité de pH lors du stockage,

comme le stockage en cours
à une humidité relative de 60 % à 75 %,
à une température de 22 °C à 30 °C, et/ou
pendant une durée de 15 semaines.

2. Produit oral à base de nicotine en sachet selon la revendication 1, dans lequel ledit sel a une solubilité dans l'eau égale ou supérieure à 0,045 M, telle qu'égale ou supérieure à 0,05 M, telle qu'égale ou supérieure à 0,06 M, telle qu'égale ou supérieure à 0,07 M, telle qu'égale ou supérieure à 0,8 M, telle qu'égale ou supérieure à 0,9 M, telle qu'égale ou supérieure à 1,0 M.

3. Produit oral à base de nicotine en sachet selon la revendication 1 ou 2, dans lequel ledit sel a une solubilité dans l'eau égale ou supérieure à 2 g/L, telle qu'égale ou supérieure à 3 g/L, telle qu'égale ou supérieure à 4 g/L, telle qu'égale ou supérieure à 5 g/L, telle qu'égale ou supérieure à 10 g/L, telle qu'égale ou supérieure à 50 g/L, telle qu'égale ou supérieure à 100 g/L, telle qu'égale ou supérieure à 150 g/L, telle qu'égale ou supérieure à 200 g/L, telle qu'égale ou supérieure à 250 g/L, telle qu'égale ou supérieure à 300 g/L, telle qu'égale ou supérieure à 350 g/L, telle qu'égale ou supérieure à 400 g/L, telle qu'égale ou supérieure à 450 g/L, telle qu'égale ou supérieure à 500 g/L, telle qu'égale ou supérieure à 600 g/L, telle qu'égale ou supérieure à 700 g/L.

4. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications 1 à 3, dans lequel ladite solubilité dans l'eau est mesurée à une température de 10 °C à 40 °C, telle que de 20°C à 25°C.

5. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel A^{n-} est un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, lactate, malate, citrate, ascorbate, acétate, sulfate, nitrate, gluconate, glutamate, guanylate, inosinate, propionate, sorbate, benzoate, formiate, pangamate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, lactate, citrate, ascorbate, acétate, sulfate, nitrate, propionate, benzoate, formiate, pangamate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, lactate, citrate, acétate, sulfate, nitrate, gluconate, benzoate, formiate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, acétate, sulfate, nitrate, formiate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, acétate, sulfate, nitrate, gluconate, propionate, formiate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, lactate, sulfate, nitrate ; tel qu'un anion choisi parmi un ou plusieurs des éléments suivants : chlorure, lactate, malate, citrate, ascorbate, tartrate, acétate, gluconate, aspartate, glycinate.

6. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le matériau de remplissage ne comprend pas de matériau de tabac ou dans lequel le matériau de tabac est présent en une quantité comprise dans la plage de 0,1 % en poids à 10 % en poids, telle que de 0,1 % en poids à 5 % en poids, telle que de 0,1 % en poids à 1 % en poids, sur la base du poids total du matériau de remplissage.

7. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel la quantité d'eau est comprise dans la plage de 0,5 % en poids à 12 % en poids, telle que de 0,5 % en poids à 5 % en poids, telle que de 3 % en poids, sur la base du poids total du matériau de remplissage ou dans lequel la quantité d'eau est comprise dans la plage de 20 % en poids à 50 % en poids, telle que de 20 % en poids à 45 % en poids, sur la base du poids total du matériau de remplissage.

8. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le sel de formule (I), ou l'hydrate dudit sel, est présent en une quantité comprise dans la plage de 0,05 % en poids à 5 % en poids, telle que de 0,1 % en poids à 5 % en poids, telle que de 0,1 % en poids à 3 % en poids, telle que de 0,1 % en poids à 2 % en poids, telle que de 0,1 % en poids à 1 % en poids, sur la base du poids total du matériau de remplissage, tel que dans lequel le sel de formule (I), ou un hydrate dudit sel, est présent en une quantité comprise dans la plage de 0,05 % en poids à 0,3 % en poids, sur la base du poids total du matériau de remplissage.

9. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le Na_2CO_3, K_2CO_3, $NaHCO_3$ et/ou $KHCO_3$ de l'agent d'ajustement du pH est/sont présents en une quantité comprise dans la plage de 1 % en poids à 10 % en poids, telle que de 1,5 % en poids à 4 % en poids ou de 4 % en poids à 9 % en poids, sur la base du poids total du matériau de remplissage.

10. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel M^{2+} est Ca^{2+} ou Mg^{2+}.

11. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications 1 à 9, dans lequel M^{2+} est Mn^{2+}, Zn^{2+} ou Fe^{2+}.

12. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications 1 à 10, dans lequel le sel de formule (I) comprend ou consiste en $CaCl_2$ ou un hydrate de celui-ci.

13. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le matériau de remplissage comprend en outre du NaCl, tel que du NaCl en une quantité comprise dans la plage de 0,1 % en poids à 5 % en poids telle que de 0,1 % en poids à 3 % en poids, sur la base du poids total du matériau de remplissage.

14. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le matériau de remplissage comprend en outre du $MgCO_3$.

15. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel ledit produit ne comprend plus de sel et/ou aucun autre régulateur de pH.

16. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel ledit matériau de remplissage dudit produit oral à base de nicotine en sachet a un pH de 7 à 10, tel que de 8 à 9, tel que de 8, 8,3, 8,5 ou 8,8, lorsqu'il est dispersé dans de l'eau purifiée.

17. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel au moins une partie du matériau de remplissage est insoluble dans l'eau.

18. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le matériau particulaire non-tabac comprend de la cellulose microcristalline et éventuellement du maltitol.

19. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le matériau de remplissage comprend une ou plusieurs fibres insolubles dans l'eau choisies dans le groupe constitué de fibres de maïs, fibres d'avoine, fibres de tomate, fibres d'orge, fibres de seigle, fibres de betterave à sucre, fibres de sarrasin, fibres de blé, fibres de pois, fibres de pomme de terre, fibres de pomme, fibres de cacao, fibres de bambou, fibres d'agrumes et leur combinaison quelconque.

20. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel la source de nicotine est un ou plusieurs des éléments suivants : chlorhydrate de nicotine, dichlorhydrate de nicotine, monotartrate de nicotine, bitartrate de nicotine, bitartrate de nicotine dihydraté, sulfate de nicotine, chlorure de nicotine et de zinc monohydraté, salicylate de nicotine, polacrilex de nicotine, tel que dans lequel la source de

nicotine est du bitartrate de nicotine et/ou du bitartrate de nicotine dihydraté.

21. Produit oral à base de nicotine en sachet selon l'une quelconque des revendications précédentes, dans lequel le pH dudit matériau de remplissage dudit produit oral à base de nicotine en sachet ne dépasse pas 9,5 lors du stockage et/ou ne change pas de plus de ± 0,5 unité de pH lors du stockage.

à une humidité relative de 60 % à 75 %,
à une température de 22 °C à 30 °C, et/ou
pendant une durée de 15 semaines.

22. Utilisation d'un sel de formule (I), ou d'un hydrate dudit sel, tel que défini dans l'une quelconque des revendications précédentes pour contrôler le pH dans un produit oral à base de nicotine en sachet comprenant un matériau de remplissage, ledit matériau de remplissage comprenant ledit sel de formule (I), ou un hydrate de celui-ci, et :

- un matériau particulaire sans tabac,
- une source de nicotine,
- de l'eau en une quantité comprise dans la plage de 1 % en poids à 50 % en poids, par exemple de 1 % en poids à 45 % en poids sur la base du poids total du matériau de remplissage, et
- un agent d'ajustement du pH comprenant ou consistant en Na_2CO_3, K_2CO_3, $NaHCO_3$ et/ou $KHCO_3$, et
- éventuellement un matériau de tabac compris dans la plage de 0,05 % en poids à 10 % en poids sur la base du poids total du matériau de remplissage,

lorsque ledit produit est stocké, tel que stocké
à une humidité relative de 60 % à 75 %,
à une température de 22 °C à 30 °C, et/ou
pendant une durée de 15 semaines.

23. Utilisation selon la revendication 22, dans laquelle ledit contrôle comprend ou consiste à atténuer une augmentation du pH dans ledit produit, empêchant le pH dans ledit produit de dépasser une valeur de 9,5, et/ou empêchant le pH dans ledit produit de changer de plus de ± 0,5 unités de pH.

24. Utilisation selon la revendication 22 ou 23, dans laquelle le sel de formule (I) est tel que défini dans l'une quelconque des revendications 1 à 5.

25. Utilisation selon l'une quelconque des revendications 22 à 24, dans laquelle le sel de formule (I), Na_2CO_3, $NaHCO_3$, K_2CO_3 et/ou $KHCO_3$ est/sont présents en une quantité totale de 1 % en poids à 15 % en poids, tel que de 1 % en poids à 10 % en poids, tel que de 1 % en poids à 9 % en poids, tel que de 1 à 7 % en poids ou tel que de 1 % en poids à 5 % en poids, sur la base du poids total du matériau de remplissage.

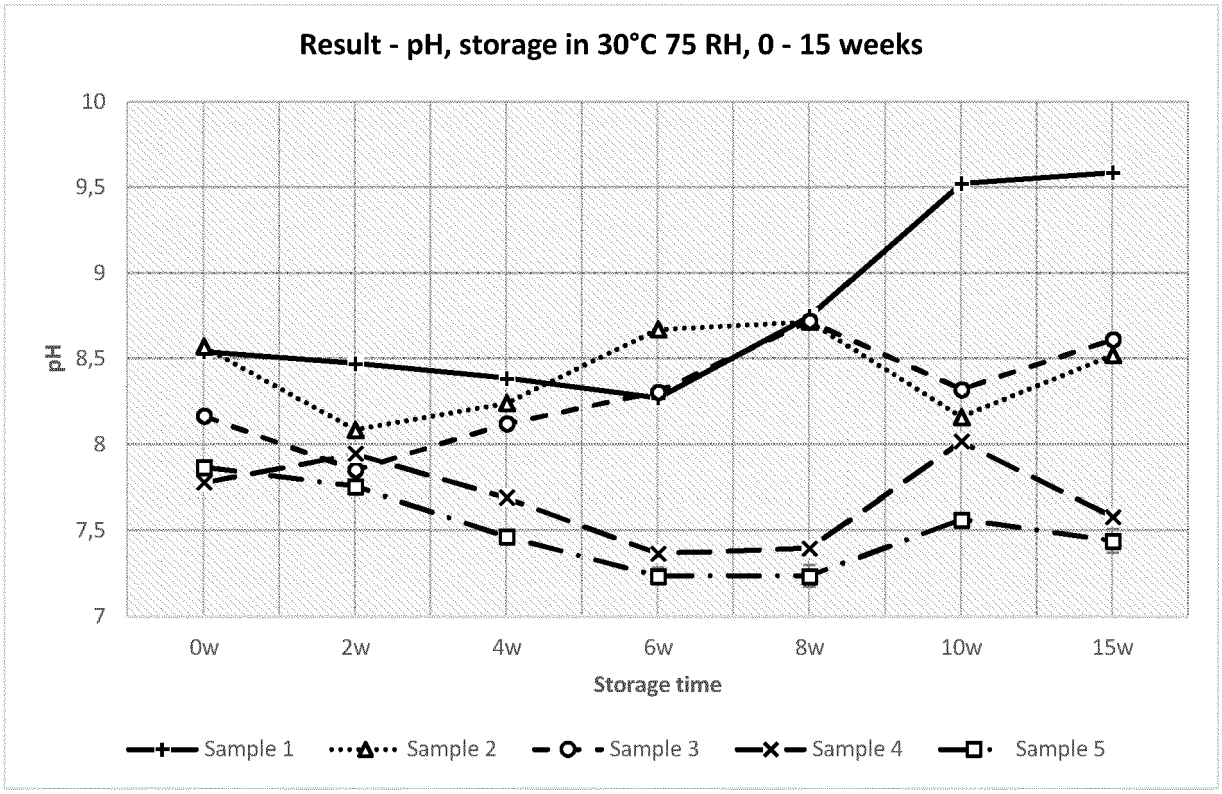
Result - pH, storage in 30°C 75 RH, 0 - 15 weeks
10
9,5
9
8,5
8
7,5
7
pH
0w
2w
4w
6w
8w
10w
15w
Storage time
Sample 1
Sample 2
Sample 3
Sample 4
Sample 5

Figure 1

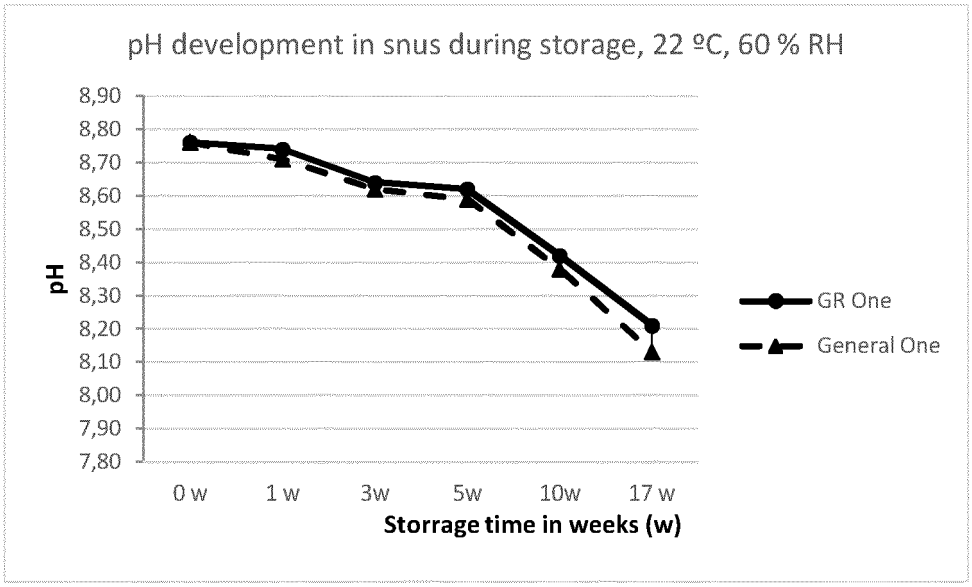
pH development in snus during storage, 22 ºC, 60 % RH
8,90
8,80
8,70
8,60
8,50
8,40
8,30
8,20
8,10
8,00
7,90
7,80
pH
0 w
1 w
3w
5w
10w
17 w
Storrage time in weeks (w)
GR One
General One

Figure 2

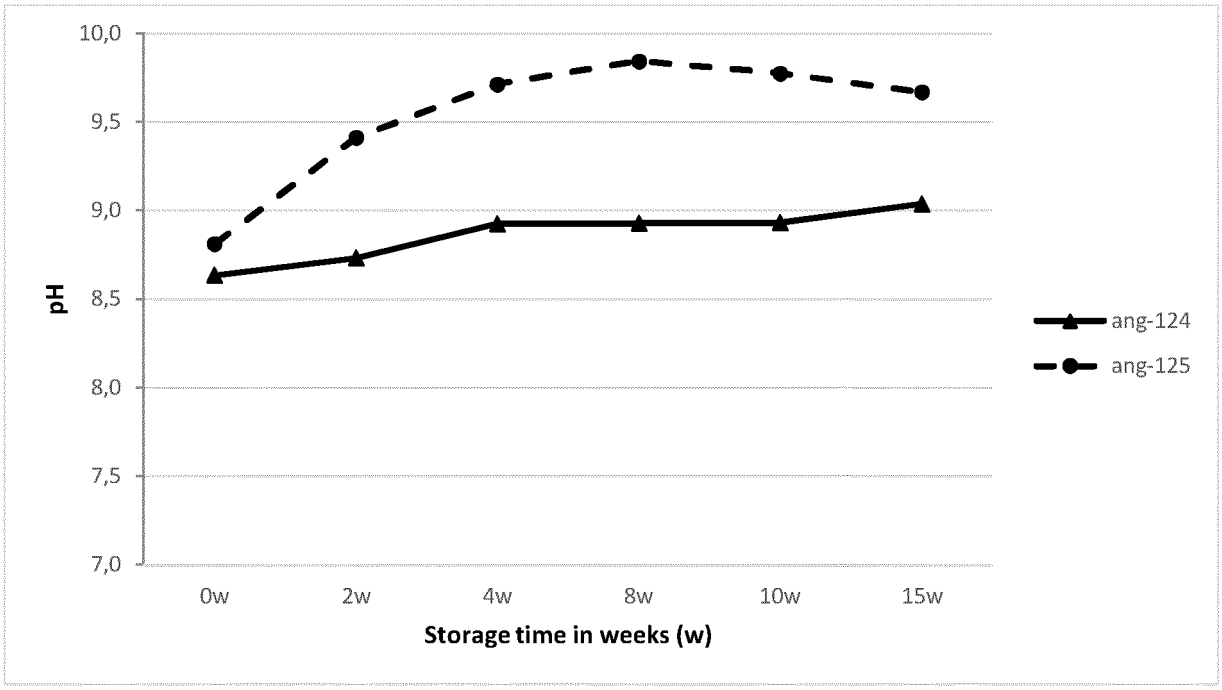
10,0
9,5
9,0
8,5
8,0
7,5
7,0
pH
0w
2w
4w
8w
10w
15w
Storage time in weeks (w)
ang-124
ang-125

Figure 3

REFERENCES CITED IN THE DESCRIPTION

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