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(54) **AEROSOLISABLE FORMULATION**

(57) There is provided an aerosolisable formulation
comprising (i) water in an amount of at least 85 wt.%
based on the aerosolisable formulation; and (ii) nicotine.
There is also provided a process for forming an aerosol,

the process comprising aerosolising an aerosolisable for-
mulation comprising (i) water in an amount of at least 85
wt.% based on the aerosolisable formulation; and (ii) nic-
otine or one or more flavours.

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Description**FIELD OF THE INVENTION**

5 **[0001]** The present disclosure relates to an aerosolisable formulation, a method of forming the same, a container containing the same, a device containing the same and processes and uses of the same.

BACKGROUND TO THE INVENTION

10 **[0002]** Electronic aerosol provision systems such as e-cigarettes generally contain a reservoir of liquid which is to be vaporised, typically containing nicotine. When a user inhales on the device, a heater is activated to vaporise a small amount of liquid, which is therefore inhaled by the user.

[0003] The use of e-cigarettes in the UK has grown rapidly, and it has been estimated that there are now over a million people using them in the UK.

15 **[0004]** One challenge faced in providing such systems is to provide from the aerosol provision device an aerosol to be inhaled which provides consumers with an acceptable experience. Some consumers may prefer an e-cigarette that generates an aerosol that closely 'mimics' smoke inhaled from a tobacco product such as a cigarette. Aerosols from e-cigarettes and smoke from tobacco products such as cigarettes provides to the user a complex chain of flavour in the mouth, nicotine absorption in the mouth and throat, followed by nicotine absorption in the lungs. These various aspects are described by users in terms of flavour, intensity/quality, impact, irritation/smoothness and nicotine reward. Nicotine contributes to a number of these factors, and is strongly associated with factors such as impact, irritation and smoothness; these are readily perceived by consumers, and e-cigarettes may offer too much or too little of these parameters for consumers, depending upon individual preferences. Nicotine reward is particularly complex as it results from both the amount of and speed with which nicotine is absorbed from the lining of the mouth, this is typically nicotine in the vapour phase, and from the amount and speed nicotine that is absorbed from the lungs, this is typically nicotine in the particulate phase of the aerosol which is inhaled. Each of these factors, and their balance, can strongly contribute to consumer acceptability of an e-cigarette. Providing means to optimise the overall vaping experience is therefore desirable to e-cigarette manufacturers.

25 **[0005]** A further challenge facing such systems is the continued demand for harm reduction. Harm from cigarette and e-cigarette devices primarily comes from toxicants. Therefore, there is a desire to reduce or remove the components which may form toxicants.

SUMMARY OF THE INVENTION

35 **[0006]** In one aspect there is provided an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine. In this aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation may contain no flavours that can be encapsulated by the one or more cyclodextrins.

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[0007] In one aspect there is provided an aerosolisable formulation comprising

- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

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[0008] In one aspect there is provided a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours. In this aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation may contain no flavours that can be encapsulated by the one or more cyclodextrins.

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[0009] In one aspect there is provided a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

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- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

[0010] In one aspect there is provided a contained aerosolisable formulation comprising (a) a container; and (b) an aerosolisable formulation , comprising (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and (ii) nicotine. In this aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation may contain no flavours that can be encapsulated by the one or more cyclodextrins.

[0011] In one aspect there is provided a contained aerosolisable formulation comprising

- (a) a container; and
- (b) an aerosolisable formulation , comprising

- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

[0012] In one aspect there is provided an electronic aerosol provision system comprising:(a) an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system;(b) a power supply comprising a cell or battery for supplying power to the aerosoliser (c) an aerosolisable formulation , comprising (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and(ii) nicotine or one or more flavours. In this aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation may contain no flavours that can be encapsulated by the one or more cyclodextrins.

[0013] In one aspect there is provided an electronic aerosol provision system comprising:

- (a) an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system;
- (b) a power supply comprising a cell or battery for supplying power to the aerosoliser
- (c) an aerosolisable formulation, comprising

- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

DETAILED DESCRIPTION

[0014] As discussed herein is provided an aerosolisable formulation comprising (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and (ii) nicotine. There is further provided a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours.

[0015] We have found that an advantageous system may be provided in which an aerosolisable formulation contains a very high content of water and is used to deliver nicotine and/or flavour.

[0016] We have surprising found that the very high water content provides a sensory perception for the user which is desirably close to the nicotine 'hit' and/or flavour release provided by tobacco based cigarettes. This desirable nicotine 'hit' and/or flavour release is in contrast to 'traditional' e-liquids based on glycerol and propylene glycol which users sometimes do not use because of the perceived differences in respect of nicotine 'hit' and/or flavour release provided by tobacco based cigarettes.

[0017] We have also identified that water-based system may be provided in which aerosolised formulation is formed from an aerosolisable formulation at a low temperature. This is in contrast to 'traditional' e-cigarettes which use a heater, typically applied to liquids based on glycerol and propylene glycol to form an aerosolised formulation. The provision of such a system and the avoidance of heating may address problems of the prior art relating to the formation of toxicants. More specifically, we have identified a water-based system which, by selection of a very high water content delivers desirable nicotine 'hit' and/or flavour release but avoids the need to use the heaters associated with prior liquids based on glycerol and propylene glycol. In the present system, the number of components present may be reduced leading to less chance of forming breakdown products/toxicants. In particular, the use of water allows for the replacement of some or all of the glycerol, propylene glycol, 1,3-propane diol and mixtures thereof typically used in e-cigarettes.

[0018] For ease of reference, these and further aspects of the present invention are now discussed under appropriate section headings. However, the teachings under each section are not necessarily limited to each particular section.

Water

[0019] As discussed herein the aerosolisable formulation comprises water in an amount of at least 85 wt.% based on

combined amount of no greater than 0.01 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains no glycerol, propylene glycol, and mixtures thereof.

[0023] In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 10 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 8 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 5 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 2 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 1 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 0.5 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 0.2 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 0.1 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains glycerol in an amount of no greater than 0.01 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains no glycerol.

[0024] In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 10 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 8 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 5 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 2 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 1 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 0.5 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 0.2 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 0.1 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains propylene glycol in an amount of no greater than 0.01 wt.% based on the aerosolisable formulation. In one aspect the aerosolisable formulation contains no propylene glycol.

Acid

[0025] In one aspect the aerosolisable formulation further comprises an acid. The acid may be any suitable acid. In one aspect the acid is an organic acid. In one aspect the acid is a carboxylic acid. In one aspect the acid is an organic carboxylic acid.

[0026] In one aspect the acid is selected from the group consisting of acetic acid, lactic acid, formic acid, citric acid, benzoic acid, pyruvic acid, levulinic acid, succinic acid, tartaric acid, sorbic acid, propionic acid, phenylacetic acid, and mixtures thereof. In one aspect the acid is selected from the group consisting of citric acid, benzoic acid, levulinic acid, lactic acid, sorbic acid, and mixtures thereof. In one aspect the acid is selected from the group consisting of citric acid, benzoic acid, levulinic acid, and mixtures thereof. In one aspect the acid is at least citric acid. In one aspect the acid consists of citric acid.

[0027] In one aspect the acid is selected from acids having a pka of from 2 to 5. In one aspect the acid is a weak acid. In one aspect the acid is a weak organic acid.

[0028] The acid may be present in any suitable amount. In one aspect the acid is present in an amount of no greater than 6 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.01 to 6 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.02 to 6 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.05 to 6 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.01 to 5 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.02 to 5 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.05 to 5 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.08 to 5 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of no greater than 4 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.01 to 4 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.02 to 4 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.05 to 4 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.08 to 4 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of no greater than 3 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.01 to 3 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.02 to 3 wt% based on the aerosolisable formulation. In one aspect the acid is present in an amount of from 0.05 to 3 wt% based on the aerosolisable formulation.

[illegible]

[0029] In one aspect the acid has a solubility in water of at least 2g/L at 20 °C. In one aspect the acid has a solubility in water of at least 5g/L at 20 °C. In one aspect the acid has a solubility in water of at least 10g/L at 20 °C. In one aspect the acid has a solubility in water of at least 20g/L at 20 °C. In one aspect the acid has a solubility in water of at least 50g/L at 20 °C. In one aspect the acid has a solubility in water of at least 100g/L at 20 °C. In one aspect the acid has a solubility in water of at least 200g/L at 20 °C. In one aspect the acid has a solubility in water of at least 300g/L at 20 °C. In one aspect the acid has a solubility in water of at least 400g/L at 20 °C. In one aspect the acid has a solubility in water of at least 500g/L at 20 °C. In one aspect the acid has a solubility in water of at least 600g/L at 20 °C. In one aspect the acid has a solubility in water of at least 700g/L at 20 °C. In one aspect the acid has a solubility in water of at least 800g/L at 20 °C. In one aspect the acid has a solubility in water of at least 900g/L at 20 °C. In one aspect the acid has a solubility in water of at least 1000g/L at 20 °C. In one aspect the acid has a solubility in water of at least 1100g/L at 20 °C.

[0030] The amount of acid and the solubility of the acid may be selected such that a given amount of the acid will dissolve in the water. In one aspect at 20 °C at least 20% of the acid dissolves in the water. In one aspect at 25 °C at least 20% of the acid dissolves in the water. In one aspect at 30 °C at least 20% of the acid dissolves in the water. In one aspect at 20 °C at least 35% of the acid dissolves in the water. In one aspect at 20 °C at least 40% of the acid dissolves in the water. In one aspect at 20 °C at least 45% of the acid dissolves in the water. In one aspect at 20 °C at least 50% of the acid dissolves in the water. In one aspect at 20 °C at least 55% of the acid dissolves in the water.

[0031] In the aspects of the invention that nicotine is present, the molar ratio of acid to nicotine may be selected as desired. In one aspect the molar ratio of acid to nicotine is from 5:1 to 1:5. In one aspect the molar ratio of acid to nicotine is from 4:1 to 1:4. In one aspect the molar ratio of acid to nicotine is from 3:1 to 1:3. In one aspect the molar ratio of acid to nicotine is from 2:1 to 1:2. In one aspect the molar ratio of acid to nicotine is from 1.5:1 to 1:1.5. In one aspect the molar ratio of acid to nicotine is from 1.2:1 to 1:1.2. In one aspect the molar ratio of acid to nicotine is from 5:1 to 1:1. In one aspect the molar ratio of acid to nicotine is from 4:1 to 1:1. In one aspect the molar ratio of acid to nicotine is from 3:1 to 1:1. In one aspect the molar ratio of acid to nicotine is from 2:1 to 1:1. In one aspect the molar ratio of acid to nicotine is from 1.5:1 to 1:1. In one aspect the molar ratio of acid to nicotine is from 1.2:1 to 1:1.

[0032] In one aspect the total content of acid present in the formulation is no greater than 5 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no greater than 4 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no greater than 3 mole

equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no greater than 2 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no greater than 1 mole equivalents based on the nicotine.

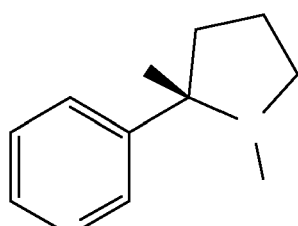
[0033] In one aspect the total content of acid present in the formulation is no less than 0.01 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.05 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.1 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.2 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.3 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.4 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.5 mole equivalents based on the nicotine. In one aspect the total content of acid present in the formulation is no less than 0.7 mole equivalents based on the nicotine.

Nicotine

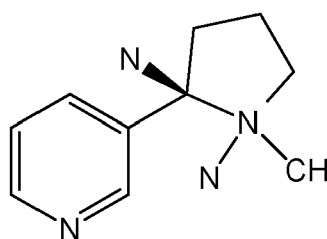
[illegible]

to 0.5 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.05 to 0.5 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.08 to 0.5 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of no greater than 0.2 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.01 to 0.2 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.02 to 0.2 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.05 to 0.2 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.08 to 0.2 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of no greater than 0.1 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.01 to 0.1 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.02 to 0.1 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.05 to 0.1 wt% based on the total weight of the aerosolisable formulation. In one aspect nicotine is present in an amount of from 0.08 to 0.1 wt% based on the total weight of the aerosolisable formulation.

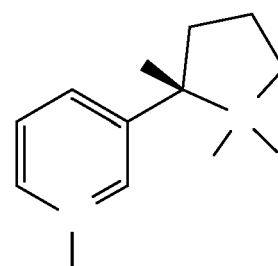
[0035] As is understood by one skilled in the art, nicotine may exist in unprotonated form, monoprotonated form or diprotonated form. The structures of each of these forms are given below.



Unprotonated nicotine



monoprotonated nicotine



diprotonated nicotine

[0036] Reference in the specification to protonated form means both monoprotonated nicotine and diprotonated nicotine. Reference in the specification to amounts in the protonated form means the combined amount of monoprotonated nicotine and diprotonated nicotine. Furthermore, when reference is made to a fully protonated formulation it will be understood that at any one time there may be very minor amounts of unprotonated nicotine present, e.g. less than 1% unprotonated.

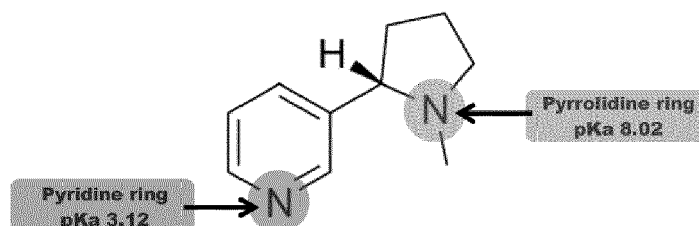
[0037] In one aspect the formulation may comprise nicotine in protonated form. In one aspect the formulation may comprise nicotine in unprotonated form. In one aspect the formulation comprises nicotine in unprotonated form and nicotine in monoprotonated form. In one aspect the formulation comprises nicotine in unprotonated form and nicotine in diprotonated form. In one aspect the formulation comprises nicotine in unprotonated form, nicotine in monoprotonated form and nicotine in diprotonated form.

[0038] In one aspect at least 5wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 10wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 15wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 20wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 25wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 30wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 35wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 40wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 45wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 50wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 55wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 60wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 65wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 70wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 75wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 80wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 85wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 90wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 95wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 99wt% of the nicotine present in the formulation is in protonated form. In one aspect at least 99.9wt% of the nicotine present in the formulation is in protonated form.

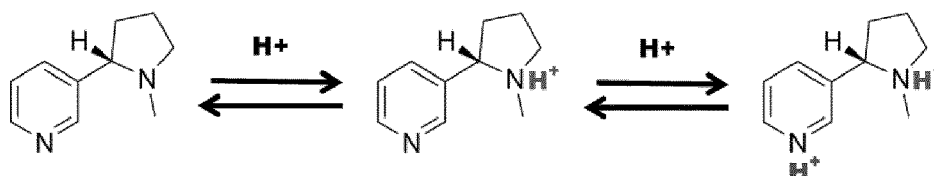
[0039] In one aspect from 50 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect

from 55 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 60 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 65 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 70 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 75 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 80 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 85 to 95 wt% of the nicotine present in the formulation is in protonated form. In one aspect from 90 to 95 wt% of the nicotine present in the formulation is in protonated form.

[0040] The relevant amounts of nicotine which are present in the formulation in protonated form are specified herein. These amounts may be readily calculated by one skilled in the art. Nicotine, 3-(1-methylpyrrolidin-2-yl) pyridine, is a diprotic base with pKa of 3.12 for the pyridine ring and 8.02 for the pyrrolidine ring. It can exist in pH-dependent protonated (mono- and di-) and non-protonated (free base) forms which have different bioavailability.

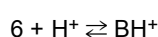


[0041] The distribution of protonated and non-protonated nicotine will vary at various pH increments.



[0042] The fraction of non-protonated nicotine will be predominant at high pH levels whilst a decrease in the pH will see an increase of the fraction of protonated nicotine (mono- or di- depending on the pH). If the relative fraction of protonated nicotine and the total amount of nicotine in the sample are known, the absolute amount of protonated nicotine can be calculated.

[0043] The relative fraction of protonated nicotine in formulation can be calculated by using the Henderson-Hasselbalch equation, which describes the pH as a derivation of the acid dissociation constant equation, and it is extensively employed in chemical and biological systems. Consider the following equilibrium:



[0044] The Henderson-Hasselbalch equation for this equilibrium is:

$$pH = pKa + \log \frac{[B]}{[BH^+]}$$

[0045] Where [B] is the amount of non-protonated nicotine (i.e. free base), [BH+] the amount of protonated nicotine (i.e. conjugate acid) and pKa is the reference pKa value for the pyrrolidine ring nitrogen of nicotine (pKa=8.02). The relative fraction of protonated nicotine can be derived from the alpha value of the non-protonated nicotine calculated from the Henderson-Hasselbalch equation as:

$$\% \text{ protonated nicotine} = 100 - \left\{ \frac{\frac{[B]}{[BH^+]}}{1 + \frac{[B]}{[BH^+]}} * 100 \right\}$$

[0046] Determination of pKa values of nicotine formulations was carried out using the basic approach described in "Spectroscopic investigations into the acid-base properties of nicotine at different temperatures", Peter M. Clayton, Carl A. Vas, Tam T. T. Bui, Alex F. Drake and Kevin McAdam, .Anal. Methods, 2013,5, 81-88.

5 Flavour

[0047] As discussed herein, the aerosolisable formulation may comprise one or more flavours or flavouring components. As used herein, the terms "flavour" and "flavourant" refer to materials which, where local regulations permit, may be used to create a desired taste or aroma in a product for adult consumers. They may include extracts (e.g. liquorice, hydrangea, Japanese white bark magnolia leaf, chamomile, fenugreek, clove, menthol, Japanese mint, aniseed, cinnamon, herb, wintergreen, cherry, berry, peach, apple, Drambuie, bourbon, scotch, whiskey, spearmint, peppermint, lavender, cardamom, celery, cascarrilla, nutmeg, sandalwood, bergamot, geranium, honey essence, rose oil, vanilla, lemon oil, orange oil, cassia, caraway, cognac, jasmine, ylang-ylang, sage, fennel, piment, ginger, anise, coriander, coffee, or a mint oil from any species of the genus *Mentha*), flavour enhancers, bitterness receptor site blockers, sensorial receptor site activators or stimulators, sugars and/or sugar substitutes (e.g., sucralose, acesulfame potassium, aspartame, saccharine, cyclamates, lactose, sucrose, glucose, fructose, sorbitol, or mannitol), and other additives such as charcoal, chlorophyll, minerals, botanicals, or breath freshening agents. They may be imitation, synthetic or natural ingredients or blends thereof. They may be in any suitable form, for example, oil, liquid, or powder. The one or more flavours may be selected from the group consisting of (4-(para-methoxyphenyl)-2-butanone, vanillin, γ -undecalactone, menthone, 5-propenyl guaethol, menthol, para-mentha-8-thiol-3-one and mixtures thereof. In one aspect the flavour is at least menthol.

[0048] If present, the one or more flavours may be present in any suitable amount. In one aspect the one or more flavours are present in a total amount of no greater than 10 wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 7 wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 5 wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 4 wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 3 wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 2wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of no greater than 1wt.% based on the aerosolisable formulation.

[0049] In one aspect the one or more flavours are present in a total amount of from 0.01 to 5wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of from 0.01 to 4wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of from 0.01 to 3wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of from 0.01 to 2wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of from 0.01 to 1wt.% based on the aerosolisable formulation. In one aspect the one or more flavours are present in a total amount of from 0.01 to 0.5wt.% based on the aerosolisable formulation.

Formulation

[0050] In one aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation contains no flavours that can be encapsulated by the one or more cyclodextrins. In one aspect, if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation contains no flavours.

[0051] As will be appreciated, one or more cyclodextrins may or may not be present in any suitable amount in the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 12 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 10 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 9 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 8 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 7 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 6 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 5 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 4 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 3 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 2 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 1 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 0.1 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total

amount of no greater than 0.01 wt.% based on the aerosolisable formulation. In one aspect the one or more cyclodextrins are present in a total amount of no greater than 0.001 wt.% based on the aerosolisable formulation.

[0052] The aerosolisable formulation of the present invention may comprise one or more cyclodextrins. The one or more cyclodextrins may be selected from the group consisting of unsubstituted cyclodextrins, substituted cyclodextrins and mixtures thereof. In one aspect at least one cyclodextrin is an unsubstituted cyclodextrin. In one aspect the one or more cyclodextrins are selected from the group consisting of unsubstituted cyclodextrins. In one aspect at least one cyclodextrin is a substituted cyclodextrin. In one aspect the one or more cyclodextrins are selected from the group consisting of substituted cyclodextrins.

[0053] In one aspect the one or more cyclodextrins are selected from the group consisting of unsubstituted (α)-cyclodextrin, substituted (α)-cyclodextrin, unsubstituted (β)-cyclodextrin, substituted (β)-cyclodextrin, unsubstituted (γ)-cyclodextrin, substituted (γ)-cyclodextrin, and mixtures thereof. In one aspect the one or more cyclodextrins are selected from the group consisting of unsubstituted (β)-cyclodextrin, substituted (β)-cyclodextrin, and mixtures thereof.

[0054] In one aspect the one or more cyclodextrins are selected from the group consisting of unsubstituted (α)-cyclodextrin, unsubstituted (β)-cyclodextrin, unsubstituted (γ)-cyclodextrin, and mixtures thereof. In one aspect the one or more cyclodextrins is selected from unsubstituted (β)-cyclodextrin.

[0055] In one aspect the one or more cyclodextrins are selected from the group consisting of substituted (α)-cyclodextrin, substituted (β)-cyclodextrin, substituted (γ)-cyclodextrin, and mixtures thereof. In one aspect the one or more cyclodextrins is selected from substituted (β)-cyclodextrins. Chemical substitutions at the 2-, 3-, and 6-hydroxyl sites are envisaged, and in particular substitution at the 2-position.

[0056] In one aspect the one or more cyclodextrins are selected from the group consisting of 2-hydroxy-propyl- α -cyclodextrin, 2-hydroxy-propyl- β -cyclodextrin, 2-hydroxy-propyl- γ -cyclodextrin and mixtures thereof. In one aspect the one or more cyclodextrins is at least 2-hydroxy-propyl- α -cyclodextrin. In one aspect the one or more cyclodextrins is at least 2-hydroxy-propyl- β -cyclodextrin. In one aspect the one or more cyclodextrins is at least 2-hydroxy-propyl- γ -cyclodextrin.

[0057] 2-hydroxy-propyl derivatives of cyclodextrins, such as 2-hydroxy-propyl- β -cyclodextrin have increased solubility in water when compared to base cyclodextrins such as β -cyclodextrin.

[0058] In further aspects, the aerosolisable formulation contains cyclodextrins in a total amount of no greater than 0.001 wt.% based on the aerosolisable formulation, such as cyclodextrins in a total amount of no greater than 1×10^{-4} wt.% based on the aerosolisable formulation, such as cyclodextrins in a total amount of no greater than 1×10^{-5} wt.% based on the aerosolisable formulation, such as cyclodextrins in a total amount of no greater than 1×10^{-6} wt.% based on the aerosolisable formulation. Thus in further aspects, the present invention provides

(1) an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine;

wherein cyclodextrins are present in a total amount of from 0 to 0.001 wt.% based on the aerosolisable formulation.

(2) a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours;

wherein cyclodextrins are present in a total amount of from 0 to 0.001 wt.% based on the aerosolisable formulation.

(3) a contained aerosolisable formulation comprising

- (a) a container; and
- (b) an aerosolisable formulation, comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine;

wherein cyclodextrins are present in a total amount of from 0 to 0.001 wt.% based on the aerosolisable formulation.

(4) an electronic aerosol provision system comprising:

- (a) an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system;

- (b) a power supply comprising a cell or battery for supplying power to the aerosoliser
- (c) an aerosolisable formulation, comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours;

wherein cyclodextrins are present in a total amount of from 0 to 0.001 wt.% based on the aerosolisable formulation.

Process

[0059] As discussed herein, in one aspect there is provided a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours.

[0060] In a further aspect there is provided a process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

[0061] In the process the aerosol may be formed by a process performed at a temperature below 60°C. In the process the aerosol may be formed by a process performed at a temperature below 50°C. In the process the aerosol may be formed by a process performed at a temperature below 40°C. In the process the aerosol may be formed by a process performed at a temperature below 30°C. In the process the aerosol may be formed by a process performed at a temperature below 25°C. In the process the aerosol may be formed by a process which does not involve heating.

[0062] In the process the aerosol may be formed by applying ultrasonic energy to the aerosolisable formulation.

[0063] In one aspect the aerosol the aerosol of the aerosolised formulation has a D50 of from 2 to 6µm. References in the present specification to particle size distribution, D50, D10 or D90 refer to values measured in accordance with British and European Pharmacopoeia, 2.9.31 Particle Size Analysis By Laser Light Diffraction (see BRITISH PHARMACOPOEIA COMMISSION. (2014), British Pharmacopoeia. London, England: Stationery Office and COUNCIL OF EUROPE. (2013). European Pharmacopoeia. Strasbourg, France: Council of Europe). The terms D50, Dv50 and Dx50 are interchangeable. The terms D10, Dv10 and Dx10 are interchangeable. The terms D90, Dv90 and Dx90 are interchangeable.

[0064] In one aspect the aerosol has a D50 of from 2.5 to 6µm. In one aspect the aerosol has a D50 of from 3 to 6µm. In one aspect the aerosol has a D50 of from 3.5 to 6µm. In one aspect the aerosol has a D50 of from 4 to 6µm. In one aspect the aerosol has a D50 of from 4.5 to 6µm. In one aspect the aerosol has a D50 of from 5 to 6µm. In one aspect the aerosol has a D50 of from 2.5 to 5.5µm. In one aspect the aerosol has a D50 of from 3 to 5.5µm. In one aspect the aerosol has a D50 of from 3.5 to 5.5µm. In one aspect the aerosol has a D50 of from 4 to 5.5µm. In one aspect the aerosol has a D50 of from 4.5 to 5.5µm. In one aspect the aerosol has a D50 of from 5 to 5.5µm.

[0065] In one aspect the aerosol has a D10 of at least 0.5µm. In one aspect the aerosol has a D10 of at least 1µm. In one aspect the aerosol has a D10 of at least 2µm.

[0066] In one aspect the aerosol has a D90 of no greater than 15µm. In one aspect the aerosol has a D90 of no greater than 12µm. In one aspect the aerosol has a D90 of no greater than 10µm.

[0067] In one aspect D50 is measured after exclusion of particles having a particle size of less than 1µm. In one aspect D10 is measured after exclusion of particles having a particle size of less than 1µm. In one aspect D90 is measured after exclusion of particles having a particle size of less than 1µm.

[0068] The formulation may be contained or delivered by any means. In one aspect the present invention provides a contained aerosolisable formulation comprising (a) one or more containers; and (b) an aerosolisable formulation as defined herein. The container may be any suitable container, for example to allow for the storage or delivery of the formulation. In one aspect the container is configured for engagement with an electronic aerosol provision system. The container may be configured to become fluidly in communication with an electronic aerosol provision system so that formulation may be delivered to the electronic aerosol provision system. As described above, the present disclosure relates to container which may be used in an electronic aerosol provision system, such as an e-cigarette. Throughout the following description the term "e-cigarette" is used; however, this term may be used interchangeably with electronic aerosol provision system.

[0069] As discussed herein, the container of the present invention is typically provided for the delivery of aerosolisable

formulation to or within an e-cigarette. The aerosolisable formulation may be held within an e-cigarette or may be sold as a separate container for subsequent use with or in an e-cigarette. As understood by one skilled in the art, e-cigarettes may contain a unit known as a detachable cartomiser which typically comprises a reservoir of aerosolisable formulation, an aerosoliser such as a wick material and a heating element for vaporising the aerosolisable formulation. In some e-cigarettes, the cartomiser is part of a single-piece device and is not detachable. In one aspect the container is a cartomiser or is part of a cartomiser. In one aspect the container is not a cartomiser or part of a cartomiser and is a container, such as a tank, which may be used to deliver nicotine formulation to or within an e-cigarette.

[0070] In one aspect the container is part of an e-cigarette. Therefore in a further aspect the present invention provides an electronic aerosol provision system comprising: an aerosolisable formulation as defined herein; an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system; and a power supply comprising a cell or battery for supplying power to the aerosoliser.

[0071] The process of the present invention may comprises additional steps either before the steps listed, after the steps listed or between one or more of the steps listed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0072] The present invention will now be described in further detail by way of example only with reference to the accompanying figure in which:-

Figure 1 shows a graph illustrating variation of $p_s K_{a2}$ with nicotine concentration

[0073] The invention will now be described with reference to the following non-limiting examples.

Examples

Example 1

[0074] A series of tests were conducted using commercially available vibrating mesh nebuliser devices. The "control" device was loaded with formulation containing 90.0% (w/w) water, 8.8% (w/w) propylene glycol containing flavour, and 1.2% (w/w) nicotine.

[0075] A similar device was prepared wherein 10.0% w/w glycerol was added to the formulation, with the water content was commensurately reduced to 80.0% (w/w).

[0076] A similar device was prepared wherein 10.0% w/w propylene glycol was added to the formulation, with the water content was commensurately adjusted to 80.0% (w/w).

[0077] A similar device was prepared wherein 5.0% w/w glycerol and 5.0% (w/w) propylene glycol was added to the formulation, with the water content was commensurately adjusted to 80.0% (w/w).

[0078] A similar device was prepared wherein 20.0% w/w glycerol was added to the formulation, with the water content was commensurately reduced to 70.0% (w/w).

[0079] A similar device was prepared wherein 20.0% w/w propylene glycol was added to the formulation, with the water content was commensurately adjusted to 70.0% (w/w).

[0080] A similar device was prepared wherein 10.0% w/w glycerol and 10.0% propylene glycol was added to the formulation, with the water content was commensurately adjusted to 70.0% (w/w).

[0081] One each of these devices was presented to 8 panellists comprising e-cigarette users, and the panellists were asked to puff on the devices in a sequential monadic fashion for 5 puffs on each device. Each panellist was asked to choose a palatable flavour of their choosing to aid feedback regarding water, glycerol and propylene glycol composition.

[0082] 8 panellists preferred the formulations that did not contain propylene glycol or glycerol in a concentration higher than 10.0% (w/w). 5 people preferred the formulation in the control device and 3 people preferred the formulation with 10% glycerol.

Example 2

[0083] Three Amaretto flavoured and three non-flavoured formulations were blindly assessed by up to 9 panellists, who are experienced vapers with different nicotine tolerances. During the sensory evaluation the panellists ranked several sensory attributes such as throat irritation and chest impact from low (1) to high (9). The panellists were also asked to indicate the most favourite formulation among the tested. A series of tests were conducted using commercially available vibrating mesh nebuliser devices.

[0084] The devices were loaded with formulations containing

Formulation 1 - 82% (w/w) water, 9.4% (w/w) 2-hydroxy-propyl- β -cyclodextrin, 8% (w/w) glycerol, and 0.6% (w/w) nicotine.

Formulation 2 - 85% (w/w) water, 9.4% (w/w) 2-hydroxy-propyl- β -cyclodextrin, 5% (w/w) glycerol, and 0.6% (w/w) nicotine.

[0086] Formulation 3 - 87% (w/w) water, 9.4% (w/w) 2-hydroxy-propyl- β -cyclodextrin, 3% (w/w) glycerol, and 0.6% (w/w) nicotine.

[0087] Formulation 4 - 82% (w/w) water, 2.0% (w/w) propylene glycol containing amaretto flavour, 9.8% (w/w) glycerol, 5% (w/w) ethanol, 0.6% (w/w) nicotine and 0.6% (w/w) citric acid.

[0088] Formulation 5 - 85% (w/w) water, 2.0% (w/w) propylene glycol containing amaretto flavour, 6.8% (w/w) glycerol, 5% (w/w) ethanol, 0.6% (w/w) nicotine and 0.6% (w/w) citric acid.

[0089] Formulation 6 - 87% (w/w) water, 2.0% (w/w) propylene glycol containing amaretto flavour, 4.8% (w/w) glycerol, 5% (w/w) ethanol, 0.6% (w/w) nicotine and 0.6% (w/w) citric acid.

[0090] The summary of tested formulations is presented in the table below.

Formulation No.	Formulation Name	Water, w/w %	No panellists	Liked
1	Base 82	82	7	1
2	Base 85	85	7	5
3	Base 87	87	7	1
4	Amaretto 82	82	9	1
5	Amaretto 85	85	9	4
6	Amaretto 87	87	9	4

[0091] 5 out of 7 panellists preferred non flavoured formulation with 85% (w/w) water content, 1 out of 7 panellists preferred non flavoured formulation with 87% (w/w) water content, while only 1 panellist preferred non flavoured formulation with 82% (w/w) water content.

[0092] 8 out of 9 panellists preferred Amaretto flavoured formulation with 85% and 87% (w/w) water content, while only 1 panellist preferred Amaretto flavoured formulation with 82% (w/w) water content.

[0093] Various modifications and variations of the present invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes for carrying out the invention which are obvious to those skilled in chemistry or related fields are intended to be within the scope of the following claims.

[0094] Further aspects of the invention are described in the following numbered paragraphs:

1. An aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

2. An aerosolisable formulation according to paragraph 1 wherein water is present in an amount of at least 90 wt.% based on the aerosolisable formulation.

3. An aerosolisable formulation according to paragraph 1 or 2 wherein water is present in an amount of at least 95 wt.% based on the aerosolisable formulation.

4. An aerosolisable formulation comprising

- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

5. An aerosolisable formulation according to any one of paragraphs 1 to 4 wherein water is present in an amount of at least 99 wt.% based on the aerosolisable formulation.

6. An aerosolisable formulation according to any one of paragraphs 1 to 5 wherein the nicotine is present in an amount of no greater than 1 wt.% based on the aerosolisable formulation.

7. An aerosolisable formulation according to paragraph 6 wherein nicotine is present in an amount of from 0.01 to 0.6wt.% based on the aerosolisable formulation.

8. An aerosolisable formulation according to any one of paragraphs 1 to 7 wherein the aerosolisable formulation further comprises an acid

9. An aerosolisable formulation according to paragraph 8 wherein the acid is selected from the group consisting of acetic acid, lactic acid, formic acid, citric acid, benzoic acid, pyruvic acid, levulinic acid, succinic acid, tartaric acid, sorbic acid, propionic acid, phenylacetic acid, and mixtures thereof.

10. An aerosolisable formulation according to paragraph 8 or 9 wherein the acid is selected from the group consisting of citric acid, benzoic acid, levulinic acid, sorbic acid, lactic acid, and mixtures thereof.

11. An aerosolisable formulation according to any one of paragraphs 8 to 10 wherein the acid is at least citric acid.

12. An aerosolisable formulation according to any one of paragraphs 8 to 11 wherein the total content of acid present in the formulation is no greater than 1 mole equivalents based on the nicotine.

13. An aerosolisable formulation according to any one of paragraphs 8 to 12 wherein the total content of acid present in the solution is no less than 0.1 mole equivalents based on the nicotine.

14. An aerosolisable formulation according to any one of paragraphs 1 to 13 further comprising one or more flavours.

15. An aerosolisable formulation according to paragraph 14 wherein the one or more flavours are selected from the group consisting of (4-(para-)methoxyphenyl)-2-butanone, vanillin, γ -undecalactone, menthone, 5-propenyl guae-thol, menthol, para-mentha-8-thiol-3-one and mixtures thereof.

16. An aerosolisable formulation according to paragraph 15 wherein the flavour is at least menthol.

17. An aerosolisable formulation according to any one of paragraphs 14 to 16 wherein the one or more flavours are present in a total amount of no greater than 2wt.% based on the aerosolisable formulation.

18. An aerosolisable formulation according to any one of paragraphs 14 to 17 wherein the one or more flavours are present in a total amount of from 0.01 to 1wt.% based on the aerosolisable formulation.

19. An aerosolisable formulation according to any one of paragraphs 1 to 18 wherein if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation contains no flavours that can be encapsulated by the one or more cyclodextrins

20. An aerosolisable formulation according to any one of paragraphs 1 to 21 wherein if the aerosolisable formulation contains one or more cyclodextrins, then the aerosolisable formulation contains no flavours.

21. A process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours.

22. A process according to paragraph 21 wherein the aerosolisable formulation comprises nicotine and, optionally, one or more flavours.

23. A process according to paragraph 22 wherein the aerosolisable formulation is an aerosolisable formulation as defined in any one of paragraphs 2 to 20.

24. A process according to paragraph 21, 22 or 23 wherein the aerosol is formed by a process performed at a temperature below 50°C.

25. A process according to any one of paragraphs 21 to 24 wherein the aerosol is formed by applying ultrasonic energy to the aerosolisable formulation.

26. A contained aerosolisable formulation comprising

- (a) a container; and
- (b) an aerosolisable formulation, comprising

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- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine.

27. A contained aerosolisable formulation according to paragraph 26 wherein the aerosolisable formulation is an aerosolisable formulation as defined in any one of paragraphs 2 to 20.

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28. A contained aerosolisable formulation according to paragraph 26 or 27 wherein the container is configured for engagement with an electronic aerosol provision system.

29. An electronic aerosol provision system comprising:

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- (a) an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system;
- (b) a power supply comprising a cell or battery for supplying power to the aerosoliser
- (c) an aerosolisable formulation , comprising

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- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine or one or more flavours.

30. An electronic aerosol provision system according to paragraph 29 wherein the aerosolisable formulation comprises nicotine and, optionally, one or more flavours.

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31. An electronic aerosol provision system according to paragraph 29 or 30 wherein the aerosolisable formulation is an aerosolisable formulation as defined in any one of paragraphs 2 to 20.

Claims

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1. An aerosolisable formulation comprising

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- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation; and
- (ii) nicotine; and
- (iii) one or more cyclodextrins.

2. An aerosolisable formulation according to claim 1 wherein water is present in an amount of at least 90 wt.% based on the aerosolisable formulation, such as wherein water is present in an amount of at least 95 wt.% based on the aerosolisable formulation.

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3. An aerosolisable formulation comprising

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- (i) water in an amount of at least 95 wt.% based on the aerosolisable formulation; and
- (ii) nicotine; and
- (iii) one or more cyclodextrins.

4. An aerosolisable formulation according to any one of claims 1 to 3 wherein water is present in an amount of at least 99 wt.% based on the aerosolisable formulation.

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5. An aerosolisable formulation according to any one of claims 1 to 4 wherein the nicotine is present in an amount of no greater than 1 wt.% based on the aerosolisable formulation, such as wherein nicotine is present in an amount of from 0.01 to 0.6wt.% based on the aerosolisable formulation.

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6. An aerosolisable formulation according to any one of claims 1 to 5 wherein the aerosolisable formulation further comprises an acid, such as wherein the acid is selected from the group consisting of acetic acid, lactic acid, formic acid, citric acid, benzoic acid, pyruvic acid, levulinic acid, succinic acid, tartaric acid, sorbic acid, propionic acid, phenylacetic acid, and mixtures thereof, such as wherein the acid is selected from the group consisting of citric acid, benzoic acid, levulinic acid, sorbic acid, lactic acid, and mixtures thereof, such as wherein the acid is at least citric acid.

7. An aerosolisable formulation according to claim 6 wherein the total content of acid present in the formulation is no greater than 1 mole equivalents based on the nicotine, such as wherein the total content of acid present in the solution is no less than 0.1 mole equivalents based on the nicotine.

8. An aerosolisable formulation according to any one of claims 1 to 7 further comprising one or more flavours, such as wherein the one or more flavours are selected from the group consisting of (4-(para-)methoxyphenyl)-2-butanone, vanillin, γ -undecalactone, menthone, 5-propenyl guaethol, menthol, para-mentha-8-thiol-3-one and mixtures thereof, such as wherein the flavour is at least menthol and/or wherein the one or more flavours are present in a total amount of no greater than 2wt.% based on the aerosolisable formulation, such as wherein the one or more flavours are present in a total amount of from 0.01 to 1wt.% based on the aerosolisable formulation.

9. A process for forming an aerosol, the process comprising aerosolising an aerosolisable formulation comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation;
- (ii) nicotine or one or more flavours; and
- (iii) one or more cyclodextrins.

10. A process according to claim 9 wherein the aerosolisable formulation comprises nicotine and, optionally, one or more flavours.

11. A process according to claim 9 or 10 wherein the aerosol is formed by a process performed at a temperature below 50°C, such as wherein the aerosol is formed by applying ultrasonic energy to the aerosolisable formulation.

12. A contained aerosolisable formulation comprising

- (a) a container; and
- (b) an aerosolisable formulation, comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation;
- (ii) nicotine; and
- (iii) one or more cyclodextrins.

13. A contained aerosolisable formulation according to claim 12 wherein the container is configured for engagement with an electronic aerosol provision system.

14. An electronic aerosol provision system comprising:

- (a) an aerosoliser for aerosolising formulation for inhalation by a user of the electronic aerosol provision system;
- (b) a power supply comprising a cell or battery for supplying power to the aerosoliser
- (c) an aerosolisable formulation, comprising

- (i) water in an amount of at least 85 wt.% based on the aerosolisable formulation;
- (ii) nicotine or one or more flavours; and
- (iii) one or more cyclodextrins.

15. An electronic aerosol provision system according to claim 14 wherein the aerosolisable formulation comprises nicotine and, optionally, one or more flavours.

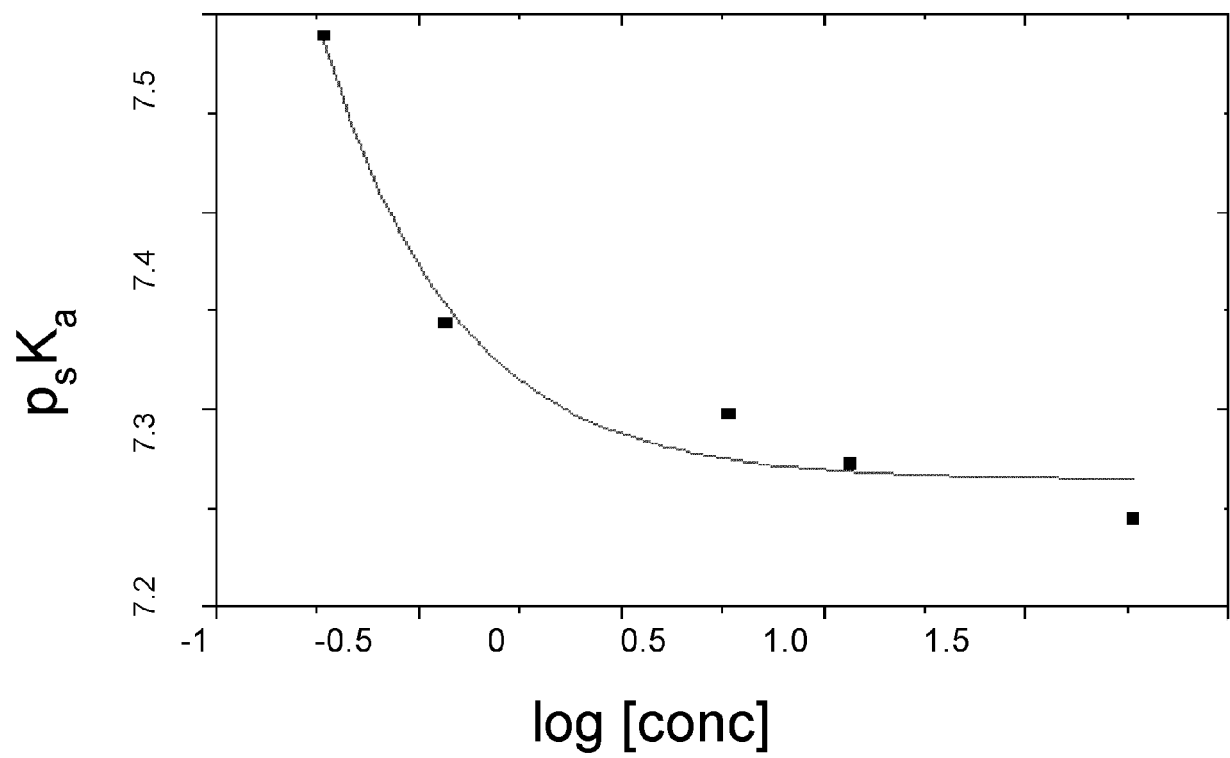


Figure 1: Variation of $p_s K_{a2}$ with nicotine concentration

REFERENCES CITED IN THE DESCRIPTION

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Non-patent literature cited in the description

- **PETER M. CLAYTON ; CARL A. VAS ; TAM T. T. BUI ; ALEX F. DRAKE ; KEVIN MCADAM.** Spectroscopic investigations into the acid-base properties of nicotine at different temperatures. *Anal. Methods*, 2013, vol. 5, 81-88 **[0046]**