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(54) SMOKELESS ARTICLE

(57) A smokeless article for oral delivery comprising a pouch enclosing a content. The content comprises a nicotinic compound, calcium lactate and sodium carbonate, wherein the pH stability of the content is such that the pH changes by less than or equal to 0.25 units over a period of 12 weeks. Typically, the content comprises 2-4 wt% calcium lactate relative to the total weight of the content, and sodium carbonate. A method of preparing the smokeless article, use of calcium lactate in the content and kits comprising the smokeless article.

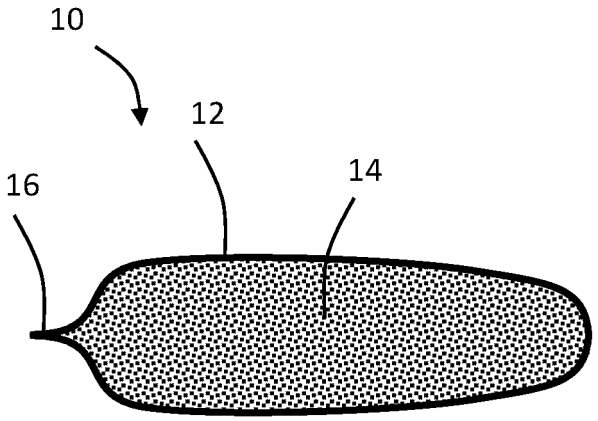

Fig. 1

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Description

FIELD

[0001] The present disclosure relates to a smokeless article. In particular, the disclosure relates to a smokeless article for oral delivery comprising a pouch enclosing a content which comprises a nicotinic compound for oral delivery. This disclosure also relates to methods of preparing the smokeless articles, use of calcium lactate in such articles, and kits comprising the smokeless article.

BACKGROUND

[0002] Smokeless articles are placed in the mouth where saliva extracts the soluble element from the content contained within. Typically, the smokeless article is placed in the oral cavity, sublingually or in the oral vestibule (between the teeth and lips/cheeks). The user may assist extraction by oral manipulation, such as by chewing and/or sucking or pressing on the outside of the mouth to squeeze the pouch.

[0003] There is a need to improve the perception of ingredients (e.g. active ingredients like nicotine) produced by smokeless articles to enhance user experience and improve the function of said ingredients. At the same time, there is a need to improve the stability of the smokeless articles over time, for example during transit and storage.

[0004] The present disclosure has been devised in the light of the above considerations.

SUMMARY

[0005] At its most general, the present disclosure relates to a smokeless article e.g. an oral nicotine delivery (OND) article, for oral delivery.

[0006] In a first aspect the present disclosure provides a smokeless article for oral delivery comprising a pouch enclosing a content, the content comprising a nicotinic compound, calcium lactate and sodium carbonate. The pH stability of the content is such that the pH changes by less than or equal to 0.25 units over a period of 12 weeks.

[0007] In some examples, the pH stability of the content is such that the pH changes by less than or equal to 0.5 units, 0.4 units, 0.3 units, 0.25 units, 0.2 units or 0.1 units over a period of 12 weeks. In some examples, the pH stability of the content is such that the pH changes by less than or equal to 0.5 units, 0.4 units, 0.3 units, 0.25 units, 0.2 units or 0.1 units over a period of 6 weeks. In some examples, the pH stability of the content is such that the pH changes by less than or equal to 0.5 units, 0.4 units, 0.3 units, 0.25 units, 0.2 units or 0.1 units over a period of 18 weeks. In some examples, the pH stability of the content is such that the pH changes by less than or equal to 0.5 units, 0.4 units, 0.3 units, 0.25 units, 0.2 units or 0.1 units over a period of 52 weeks. In some examples, the pH stability of the content is such that the pH is substantially constant over a period of 12 weeks. In some examples, the pH stability of the content is such that the pH is substantially constant over a period of 6 weeks. In some examples, the pH stability of the content is such that the pH is substantially constant over a period of 18 weeks. In some examples, the pH stability of the content is such that the pH is substantially constant over a period of 52 weeks.

[0008] The change in pH is understood to mean a positive or a negative change in pH. That is, in some examples, the pH stability reflects the extent to which the content resists a change in pH over time.

[0009] In some examples, the period of time in which pH is observed starts shortly, or immediately after the smokeless article or content is manufactured. That is, in some examples, the 12 week, 6 week, 18 week or 52 week period begins shortly or immediately after the smokeless article or content is manufactured.

[0010] In some examples, the pH stability and any associated pH change is as described above when the smokeless article is stored in packaging, for example in an air-tight cannister or container. In such a scenario, for all or substantially all of the time period in which pH is observed and pH stability is established, the smokeless article is stored in the packaging (e.g. air-tight cannister or container). In some examples, the period of time in which pH is observed starts shortly, or immediately after the smokeless article is sealed into packaging, for example into an air-tight cannister or container.

[0011] In some examples, the pH stability and any associated pH change is as described above when the smokeless article is stored under ambient conditions. In some examples, ambient conditions here refer to approximately room temperature (about 19 to 24°C) and pressure (about 1 atmosphere).

[0012] In some examples, in order to measure the pH change over a period of time, and therefore ascertain the pH stability, samples of content are taken at regular intervals, for example at 0 weeks, 4 weeks, 8 weeks and 12 weeks. In some examples, content from the same smokeless article, batch or container is used at each sampling interval. In some examples, content from different smokeless article, batches or containers are used at each sampling interval, for example a first air-tight container is opened at 4 weeks and content used for a measurement, a second container is opened at 8 weeks and content used for a second measurement and a third container is opened at 12 weeks and content used for a third measurement, and so on. In some examples the change refers to the difference in pH between the first time point and

the last time point. In some examples, the change refers to the difference in pH between any two given time points at which the content pH is measured.

[0013] To measure the pH, a sample of content is mixed with water and stirred, before taking a pH measurement using a pH probe. For example, such a pH measurement can be carried out by thoroughly mixing 2g of content with 18ml of water, including agitating the content and water for at least 5 minutes, and taking a pH measurement at ambient conditions using a Metrohm pH meter with a Unitrode Pt1000 electrode.

[0014] In some examples, the pH stability of the content results in improved shelf-life (for example, measured as no noticeable change in user perception and/or safety) of at least 6 weeks, at least 12 weeks, at least 18 weeks, at least 20 weeks, at least 24 weeks, at least 28 weeks, or at least 32 weeks.

[0015] As used herein, a "smokeless article for oral delivery" is an article that does not need to be heated or burned in order to function. The smokeless article is for oral delivery, as used herein, the term "oral delivery" is intended to refer to any oral administration route achieved by placing the smokeless article into the oral cavity. This includes, but is not limited to, buccal, sub-lingual, periodontal, gingival and ingestion.

[0016] Without wishing to be bound by theory, it is thought that the presence of calcium lactate and sodium carbonate in combination with high pH stability contributes to improved absorption of nicotine, and therefore improved nicotine perception. It is further thought that the presence of calcium lactate, particularly in combination with sodium carbonate, in the content provides or contributes significantly to the beneficial pH stability characteristics. Nicotine perception can be measured using a trained panel of testers, and asking them to report on the nicotine intensity at pre-determined time intervals.

[0017] The pH of the content is thought to affect nicotine absorption through the oral mucosa. It is important for smokeless articles to provide good nicotine absorption for a good user experience and good nicotine perception. In addition, it is beneficial that the pH does not vary significantly over time before use, as this can reduce the shelf-life of a smokeless article.

[0018] For the user to extract the nicotine and, for example, get good absorption of nicotine through the oral mucosa, the pH of the content is preferably within a range allowing it to easily cross the mucous membranes. For instance, under acidic conditions, nicotine is protonated and does not readily cross mucous membranes.

[0019] Overtime, the pH of known smokeless articles can become more acidic which can negatively impact nicotine absorption and nicotine perception experienced by the user. The change in pH can be caused or increased by the presence of certain components of the content (for example, flavourings). There exist particularly acidic flavourings which can negatively impact the pH of known content formulations. It is thought that the present invention will be particularly useful in such compositions where it is more important that the pH does not become more acidic.

[0020] Calcium lactate in the content of the first aspect acts as a pH regulator. The use of calcium lactate may help to maintain the pH in a preferred range overtime. The use of calcium lactate and sodium carbonate is particularly effective at maintaining pH in a preferred range over time.

[0021] The smokeless article comprises a pouch enclosing a content. In some examples the pouch is sealed, and in this way completely encloses the content. In some examples the pouch defines an internal volume in which the content resides in the smokeless article. In some examples the pouch encloses the content such that the content cannot leave the pouch when the smokeless article is not in use (e.g. in storage), or when it is in use and (e.g. and scatter in the oral cavity).

[0022] In some examples the pouch may be formed from one or more materials. In some examples, the pouch material may be formed from one or more of fibre, paper, cloth and fabric. In some examples, the pouch may be formed from one or more polymeric materials. In some examples, the polymeric material may be selected from one or more of hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVOH), polyvinylpyrrolidone (PVP), polyethylene oxide (PEO) hydroxyethyl cellulose (HEC), polyethylene glycol (PEG), pullulan, sodium alginate, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, maltodextrin, methylmethacrylate copolymer, carboxyvinyl copolymers, starch and gelatin.

[0023] The pouch may be formed by, for example, folding a single sheet on itself or bringing two or more sheets together and sealing the edges. The edges may initially be partially sealed to provide an open pouch in which the content may be placed before completely sealing the pouch closed. The sheets may be the same thickness or different thicknesses.

[0024] In some examples, the content of the pouch occupies substantially all of the internal volume of the pouch. The content may occupy 80%, 85%, 90%, 95% or 100% of the internal volume of the pouch.

[0025] In some examples, the pouch is porous. In some examples, at least 50% of the pores have a diameter of 50 μm to 200 μm, such as 100 μm to 175 μm or 125 μm or 150 μm. In some examples, at least 50% of the pores have a diameter of at least 100 μm. For example, in some examples at least 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95% or 100% of the pores have such diameters.

[0026] The pouch may be coloured or include markings, such as brand logos and text, to improve user perception. The pouch may be partially or completely coloured by a colourant.

[0027] The content may comprise nicotine in the form of nicotine freebase, a nicotine salt(s), a nicotine complex(es), and a nicotine solvate(s), or mixtures thereof. In some examples, nicotine salt is selected from the group consisting of nicotine

hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine ditartrate, nicotine ditartrate dihydrate, nicotine sulfate, nicotine zinc chloride monohydrate, nicotine salicylate and mixtures thereof.

[0028] In some examples, the content comprises nicotine in an amount of from 0.3 wt.% to 2 wt.%, from 0.4 wt.% to 2 wt.%, from 0.5 wt.% to 2 wt.%, from 0.5 wt.% to 1.9 wt.%, from 0.8 wt.% to 1.8 wt.%, from 1 wt.% to 1.6 wt.%, from 1.2 wt.% to 1.6 wt.%, or from 1.3 wt.% to 1.5 wt.%, based on the total weight of the content.

[0029] In some examples, the total nicotine content per pouch is from 4 to 15 mg. In some examples, the nicotine content per pouch is about 7-10 mg. In some examples the nicotine content per pouch is about 8 mg.

[0030] In some examples, the amount of water in the content is from 30 wt.% to 60 wt.%, from 30 wt.% to 55 wt.%, from 35 wt.% to 60 wt.%, from 35 wt.% to 55 wt.%, from 30 wt.% to 50 wt.%, or from 30 wt.% to 45 wt.% based on the total weight of the content.

[0031] The content comprises calcium lactate. In some examples, the calcium lactate is present at 0.1-10 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at 1-6 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at 2-5 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at 2-4 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at 2.25-3.75 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at 2.5-3.5 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2-3 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2.1-2.9 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2.2-2.8 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2.3-2.7 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2.3-2.6 wt% relative to the total weight of the content. In some examples the calcium lactate is present at 2.3-2.5 wt% relative to the total weight of the content. In some examples, the calcium lactate is present at MIN-MAX wt% wherein a single value of MIN is selected from 2, 2.05, 2.1, 2.15, 2.2, 2.25, 2.3, and 2.35, and wherein a single value of MAX is selected from 3, 2.95, 2.9, 2.85, 2.8, 2.75, 2.7, 2.65, 2.6, 2.55, 2.5, and 2.45.

[0032] It is thought that the presence of calcium lactate at 0.1-10 wt% relative to the total weight of the pouch content results in particularly improved pH stability and absorption of nicotine, and particularly improved nicotine perception. It is also thought that the presence of calcium lactate at 0.1-10 wt% relative to the total weight of the content in the presence of sodium carbonate results in particularly improved pH stability and absorption of nicotine, and particularly improved nicotine perception.

[0033] The term "calcium lactate" may be used to refer to any form of calcium lactate, in particular any hydrate or anhydrate form of calcium lactate, or any polymorphic form of calcium lactate. The term "calcium lactate" may also be used to refer to any grade of calcium lactate, for example in some cases food grade calcium lactate is used, e.g. 98% purity.

[0034] As used herein, the terms "pH regulator", "buffer", "pH stabiliser", "pH modifier", and "pH adjuster" interchangeably refer to components of the content used to control the pH. Within these definitions, the terms "pH regulator", "buffer" and "pH stabiliser" refer to compounds that have the capacity to resist pH change to some level so providing some ability to maintain pH in a specific buffer range as compared to just altering the pH.

[0035] Examples of suitable pH stabilisers that can be used in addition to calcium lactate and sodium carbonate include ammonia, ammonium carbonate, and calcium carbonate. These components may have a buffering action, which helps to maintain the pH at the desired level.

[0036] In some examples, the overall pH of the smokeless article is pH 7 to pH 10. In some examples the overall pH of the smokeless article is pH 7.5 to pH 9.5. In some examples, the overall pH of the smokeless article is pH 7.75 to pH 9.25. In some examples the overall pH of the smokeless article is pH 8 to pH 9. In some examples, the overall pH of the smokeless article is pH 7.5 to pH 8.5. Preferred pH ranges provide good nicotine absorption conditions without causing detriment to the user experience, e.g., without the content causing irritation due to its alkalinity. In some examples, the amount of sodium carbonate is such that the pH of the smokeless article is between pH 7.5 to 9.

[0037] In some examples, the smokeless article may have a mass of about 0.1 g to 5.0 g. In some examples the smokeless article has a mass of about 0.5 g to about 4.0 g. In some examples the smokeless article has a mass of about 1.0 g to about 3.0 g.

[0038] In some examples, the smokeless article has a length of about 30 mm. In some examples the smokeless article has a length of about 28 mm. In some examples, the smokeless article has a length of about 26 mm. In some examples the smokeless article has a width of about 12mm. In some examples the smokeless article has a width of about 10 mm. In some examples the smokeless article has a width of about 8 mm. In some examples the smokeless article has a depth of about 5 mm. In some examples the smokeless article has a dept of about 4 mm. In some examples the smokeless article has a depth of about 3 mm.

[0039] In some examples, the smokeless article may have an active lifetime of about 20 minutes to about 60 minutes after being placed in the mouth. In some examples, the smokeless article has an active lifetime of about 25 minutes to 50 minutes after being placed in the mouth. In some examples, the smokeless article has an active lifetime of about 30 minutes to about 45 minutes after being placed in the mouth. As used herein, the term "active lifetime" is intended to refer to the amount of time after being placed in the mouth that the smokeless article provides the user with a perceptible taste

and/or physiological experience. For example, the smokeless articles described herein comprises nicotine - the active lifetime may be defined as the in use period of time in which 90 wt% of the available nicotine is released. In other words, the active lifetime may be the duration of time from insertion into the oral cavity for 90 wt% of the total amount of nicotine that is capable of being released during normal use to dissolve into the user's saliva and /or enter the user's bloodstream. It will therefore be appreciated that the active lifetime of a product may vary from user to user and for a user based on oral conditions, in particular extent of salivation. Nonetheless, the skilled person is able to mimic oral conditions to determine the active lifetime in one instance, which can be used as a comparison or analysis point.

[0040] In some examples of the smokeless article, calcium lactate is present at 2-4 wt% relative to the total weight of the content. Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article.

[0041] In some examples of the smokeless article, calcium lactate is present at 2.25-3.75 wt% relative to the total weight of the content. Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article.

[0042] In some examples of the smokeless article, calcium lactate is present at 2.1-2.9 wt% relative to the total weight of the content. Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article.

[0043] In some examples of the smokeless article, calcium lactate is present at 2.3-2.5 wt% relative to the total weight of the content. Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article.

[0044] In some examples of the smokeless article, the calcium lactate comprises calcium lactate pentahydrate. The use of calcium lactate pentahydrate provides for particularly improved nicotine perception and pH regulation in the smokeless article. In some examples, the calcium lactate consists essentially of calcium lactate pentahydrate. In some examples, the calcium lactate is (i.e. consists of) calcium lactate pentahydrate.

[0045] In some examples of the smokeless article, the sodium carbonate is present at up to 0.1 wt% relative to the total weight of the content. Here, "up to" means "up to and including". Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article, and ensures that the formulation is not too alkaline, which may cause irritation to the user.

[0046] In some examples of the smokeless article, the sodium carbonate is present at 0.01-0.1 wt% relative to the total weight of the content. Such a range of wt% provides for particularly improved nicotine perception and pH regulation in the smokeless article, ensuring enough sodium carbonate is present to be effective at regulating pH, and ensuring the formulation is not too alkaline, which may cause irritation to a user.

[0047] The term "sodium carbonate" may be used to refer to sodium bicarbonate, sodium carbonate, and mixtures thereof. In some examples, "sodium carbonate" is sodium carbonate. In some examples "sodium carbonate" is sodium bicarbonate. In some examples, "sodium carbonate" is a mixture of sodium carbonate and sodium bicarbonate.

[0048] Particular benefits may be obtained when both calcium lactate and sodium carbonate are present in the stated ranges. In those cases, nicotine perception may be particularly improved (e.g. as tested by user acceptance) and pH regulation may be particularly effective.

[0049] In some examples, the content further comprises a filler.

[0050] In some examples, the filler comprises one or more natural fibres. In some examples the natural fibres comprise one or more of micro-crystalline cellulose, wheat fibre, bamboo fibre, apple fibre, citrus fibre, sugar cane fibre, rice fibre, psyllium fibre, potato fibre, pea fibre, and oat fibre.

[0051] Fillers may be provided to increase the volume of the smokeless article (e.g. by increasing the volume contained within the pouch and to strengthen the content).

[0052] In general, suitable fillers include calcium carbonate, calcium phosphate, corn starch, grains, lactose, polysaccharides (e.g. maltodextrin), polyols, sugars (e.g. dextrose, manitol, xylitol, sorbitol), natural fibres (e.g. non-tobacco fibres), microcrystalline cellulose, cellulose and cellulose derivatives (e.g. finely divided cellulose), lignocellulose fibres (e.g. wood fibres), jute fibres and combinations thereof. In some cases the filler comprises wheat fibres. In some cases the filler comprises bamboo fibres. The use of a filler is able to improve the overall mouth-feel of the smokeless article.

[0053] In some cases the filler comprises micro-crystalline cellulose and one of wheat fibres or bamboo fibres.

[0054] In some cases, the filler content is about 30 to 70 wt% of the content. In some examples, the filler content is about 40 to 60 wt% of the content.

[0055] In some examples, the content comprises plant material. In some examples, the plant material functions as a filler.

[0056] Plant material may be provided for physical integrity and may function as a natural source of substances such as, for example, biologically/pharmacologically active compounds, flavourings, pH stabilisers etc. The plant material may comprise at least one plant material selected from the list including *Amaranthus dubius, Arctostaphylos uva-ursi* (Bearberry), *Argemone mexicana, Amica, Artemisia vulgaris,* Yellow Tees, *Galea zacatechichi, Canavalia maritima* (Baybean), *Cecropia mexicana* (Guamura), *Cestrum noctumum, Cynoglossum virginianum* (wild comfrey), *Cytisus*

scoparius, Damiana, Entada rheedii, Eschscholzia califomica (California Poppy), *Fittonia albivenis, Hippobroma longiflora, Humulus japonica* (Japanese Hops), *Humulus lupulus* (Hops), *Lactuca virosa* (Lettuce Opium), *Laggera alata, Leonotis leonurus, Leonurus cardiaca* (Motherwort), *Leonurus sibiricus* (Honeyweed), *Lobelia cardinalis, Lobelia inflata* (Indian-tobacco), *Lobelia siphilitica, Nepeta cataria* (Catnip), *Nicotiana species* (Tobacco), *Nymphaea alba* (White Lily), *Nymphaea caerulea* (Blue Lily), Opium poppy, *Passiflora incamata* (Passionflower), *Pedicularis densiflora* (Indian Warrior), *Pedicularis groenlandica* (Elephant's Head), *Salvia divinorum, Salvia dorrii* (Tobacco Sage), Salvia species (Sage), *Scutellaria galericulata, Scutellaria lateriflora, Scutellaria nana, Scutellaria* species (Skullcap), *Sida acuta* (Wireweed), *Sida rhombifolia, Silene capensis, Syzygium aromaticum* (Clove), *Tagetes lucida* (Mexican Tarragon), *Tarchonanthus camphoratus, Tumera diffusa* (Damiana), *Verbascum* (Mullein), *Zamia latifolia* (Maconha Brava) together with any combinations, functional equivalents to, and/or synthetic alternatives of the foregoing.

[0057] In some examples, the filler may have a particle size of 10-500 μm, 10-450 μm, 10-400 μm, 10-350 μm, 10-300 μm, 10-250 μm, 10-200 μm, 10-150 μm, 10-100 μm, 10-50 μm, 15-50 μm, 10-450 μm, 15-45 μm, 20-50 μm, 20-45 μm, 20-40 μm, or 25-35 μm.

[0058] In some examples, the filler may have a particle size of 15-500 μm, 20-500 μm, 50-500 μm, 100-500 μm, 150-500 μm, 200-500 μm, 250-500 μm, 250-450 μm, 250-400 μm, 250-350 μm, 260-340 μm, 270-330 μm, 280-320 μm, 290-310 μm, or 295-305 μm.

[0059] As used herein, the term "particle size" when referring to fibres may indicate the maximum size of the longest dimension of the fibres. For example, a particle size of 50 μm indicates that in the population of fibres, the maximum fibre length is 50 μm. Alternatively, the term "particle size" when referring to fibres may indicate the average size of the longest dimension of the fibres.

[0060] Particles having the desired particle size may be obtained by passing a population of fibres through a sieve of corresponding mesh size. For example, to obtain fibres of particle size 300 μm (i.e. a maximum fibre length of 300 μm), a population of fibres are passed through a sieve with 300 μm diameter apertures in the mesh. In this way, fibres with a length of 300 μm or less pass through the mesh and fibres longer than 300 μm are retained by the mesh. The fibres which pass through the mesh may then be used in the smokeless article of the invention, having a particle size of 300 μm. Fibres of a desired particle size are also available from commercial suppliers such as Jelu-werk.

[0061] Colourants may be provided to modify the user impression of the smokeless article. Colourants include whitening agents. Colourants may be selected from one or more of common colourants such as curcumin (E100), turmeric (E100(ii)), riboflavin (E101), riboflavin-5'-phosphate (E101(ii)), tartrazine (E102), quinoline yellow (E104), riboflavin-5-sodium phosphate (E106), yellow 2G (E107), sunset yellow FCF (E110), carmine, cochineal (E120), azorubine (E122), amaranth (E123), ponceau 4R (E124), erythrosine (E127), red 2G (E128), allura red AC (E129), patent blue V (E131), indigotine (E132), brilliant blue FCF (E133) chlorophylls (E140), copper complexes of chlorophyll (E141), green S (E142), caramel (E150a-d), brilliant black BN (E151), carbon (E153), brown FK (E154), brown HT (E155), alfa-, beta- and gamma- carotene (E160a), annatto, bixin, norbixin (E160b), bell pepper (Paprika) extract (E160c), lycopene (E160d), beta- apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'-carotenic acid (E160f), flavoxanthin (E161a), lutein (E161b), cryptoxanthin (E161c), rubixanthin (E161d), violaxanthin (E161e), rhodoxanthin (E161f), canthaxanthin (E1619), citranaxanthin (E161h), beetroot extract (E162), anthocyanins (E163), calcium carbonate (E170), titanium dioxide (E171), iron oxides (E172), aluminium (E173), silver (E174), gold (E175), lithol rubine BK (E180), tannins (E181). The amount of colourant may be up to about 3% by weight of the smokeless article, such as about 0.5% to about 2.5% or about 1% to about 2%.

[0062] In some examples of the smokeless article, the content comprises a flavouring.

[0063] Flavouring may be provided in solid or liquid form. Suitable flavourings include coffee, eucalyptus, menthol, liquorice, peppermint, spearmint, chocolate, fruit flavour (including e.g. citrus, cherry etc.), vanilla, spice (e.g. ginger, cinnamon) and tobacco flavour. The flavouring may be evenly dispersed throughout the content or may be provided in isolated locations and/or varying concentrations throughout the content. As used herein, the term "flavouring" denotes a compound having a desirable taste, aroma or both.

[0064] In some examples, the content comprises one or more flavourings (e.g. peppermint flavour) in an amount of from above 0 wt.% to 10 wt.%, from 1 wt.% to 10 wt.%, from 1 wt.% to 8 wt.%, from 1 wt.% to 6 wt.%, from 2 wt.% to 8 wt.%, from 2 wt.% to 7 wt.%, or from 3 wt.% to 7 wt.% based on the total weight of the content.

[0065] In some smokeless articles flavouring materials included in the content may cause the content to become more acidic. Therefore, the present proposals may be particularly effective for acidic flavour components. In cases where the flavouring materials have a greater impact on the pH of the content the use of a combination of pH regulators selected from the list of sodium carbonate, sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate may be particularly useful to control the pH to within a desired range.

[0066] In some examples the content comprises less than 5 wt% tobacco. "Tobacco" as used herein refers to tobacco, or any tobacco derived product.

[0067] In some examples the content is free of tobacco. In this way, the user may experience a similar or enhanced recreational/pharmaceutical effect as compared to conventional tobacco-containing products without experiencing

undesirable components inherent to tobacco (e.g. tobacco flavour).

[0068] In some examples of the smokeless article, the content comprises one or more salts.

[0069] Salts may be provided to maintain the osmolarity of the content within the smokeless article/pouch. Salts contribute to the overall positive user experience of the smokeless article, such as pleasant mouth feel. Examples of salts which may be used include sodium chloride, potassium chloride, magnesium chloride and calcium chloride.

[0070] In some examples of the smokeless article, the content comprises biologically and/or pharmaceutically active compounds.

[0071] Biologically/pharmacologically active compounds are provided to produce a pharmacological effect in the user. Suitable biologically/pharmacologically active compounds include the group consisting of: nicotine, cocaine, caffeine, opiates and opioids, cathine and cathinone, kavalactones, mysticin, beta-carboline alkaloids, salvinorin A, together with any combinations, functional equivalents to, and/or synthetic alternatives of the foregoing. Biologically/pharmacologically active compounds may also have additive properties. In some examples, biologically / pharmaceutically active compounds are present at 1-3 wt% relative to the total weight of the content.

[0072] In some examples of the smokeless article, the content comprises a humectant.

[0073] Humectants may be provided to control moisture content thereby preventing the smokeless article from drying out during storage and reducing the amount of saliva wetting required before the user experience begins. Suitable humectants include polyhydric alcohols (e.g. propylene glycol (PG), triethylene glycol, 1,2-butane diol and glycerol such as vegetable glycerine (VG)) and their esters (e.g. glycerol mono-, di- or tri-acetate). The humectant component may consist of a single humectant compound or may consist of two or more different humectant compounds.

[0074] In some examples of the smokeless article, the content comprises a sweetener.

[0075] Sweeteners may be provided to modify the user taste perception and, in particular, overcome bitter flavours that result from other substances. Suitable sweeteners include honey, sugar, brown sugar, glucose, fructose, sucrose, aspartame, xylitol, maltitol, saccharin sodium, glycyrrhizin tripotassium liquorice, jujube, acesulfame K, or a mixture thereof. In some cases the sweetener may be xylitol.

[0076] In some examples, the content comprises a sweetener in an amount of from 0 wt.% to 5 wt.%, from 0.01 wt.% to 4 wt.%, from 0.01 wt.% to 3 wt.%, from 0.5 wt.% to 3 wt.%, or from 1 wt.% to 3 wt.% based on the total weight of the content.

[0077] In some examples of the smokeless article, the content comprises a stabiliser.

[0078] Stabilisers are provided to prevent decomposition or degradation over time during storage by, for example, retarding oxidation or unwanted biological activity. Stabilisers may be selected from the group consisting of antioxidants including vitamin E, such as tocopherole, ascorbic acid, sodium pyrosulfite, butylhydroxytoluene, butylated hydroxyanisole, edetic acid and salts thereof; and preservatives including citric acid, tartaric acid, lactic acid, malic acid, acetic acid, benzoic acid, sorbic acid and salts thereof.

[0079] In some examples of the smokeless article, the content comprises a binder.

[0080] Binders may be provided. Suitable binders include starches and/or cellulosic binders such as methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose and carboxymethyl cellulose, gums such as xanthan, guar, arabic and/or locust bean gum, organic acids and their salts such as alginic acid (sodium alginate), agar and pectins.

[0081] In a second aspect the present disclosure provides a method of preparing a smokeless article according to the first aspect, comprising a blending step.

[0082] In some examples, the method further comprises a preceding step of weighing all materials which make up the content into appropriately sized beakers.

[0083] In some examples, the blending step comprises blending calcium lactate with other solid components. In some examples, the blending step comprises blending calcium lactate and sodium carbonate with one or more components selected from a filler, a salt, a sweetener, a binder, a stabiliser, a biologically / pharmaceutically active compound and plant material.

[0084] In some examples the filler is one or more selected from a wheat fibre and microcrystalline cellulose.

[0085] In some examples the sweetener is one or more selected from xylitol and acesulfame K.

[0086] In some examples, whilst the blending step is on-going, nicotine in water and flavouring is added.

[0087] In some examples, the content produced is filled into open or partially unformed pouches. In some examples the pouches are then sealed.

[0088] In a third aspect, the present disclosure provides the use of calcium lactate in the content of the smokeless article according to the first aspect to improve nicotine perception by a user.

[0089] In a fourth aspect, the present disclosure provides a kit comprising a plurality of smokeless articles according to the first aspect. In some examples the kit comprises 2 to 20 smokeless articles.

[0090] The preceding summary is provided for purposes of summarizing some examples to provide a basic understanding of aspects of the subject matter described herein. Accordingly, the above-described features should not be construed to narrow the scope or spirit of the subject matter described herein in any way. Moreover, the above and/or proceeding examples may be combined in any suitable combination to provide further examples, except where such a combination is clearly impermissible or expressly avoided. Other features, aspects, and advantages of the subject matter

described herein will become apparent from the following text and the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

[0091] Aspects, features and advantages of the present disclosure will become apparent from the following description of examples in reference to the appended drawings in which like numerals denote like elements.

Fig. 1 shows a cross sectional view of a first embodiment of a smokeless article.
Fig. 2 shows a cross sectional view of a second embodiment of a smokeless article.
Fig. 3 shows a cross sectional view of a third embodiment of a smokeless article.
Fig. 4 shows a cross sectional view of a fourth embodiment of a smokeless article.
Fig. 5 shows a plot of pH vs time for two contents within the scope of the claims, and two contents outside of the scope of the claims.

DETAILED DESCRIPTION OF EMBODIMENTS

[0092] Before describing several examples implementing the present disclosure, it is to be understood that the present disclosure is not limited by specific construction details or process steps set forth in the following description and accompanying drawings. Rather, it will be apparent to those skilled in the art having the benefit of the present disclosure that the systems, apparatuses and/or methods described herein could be embodied differently and/or be practiced or carried out in various alternative ways.

[0093] Unless otherwise defined herein, scientific and technical terms used in connection with the presently disclosed inventive concept(s) shall have the meanings that are commonly understood by those of ordinary skill in the art, and known techniques and procedures may be performed according to conventional methods well known in the art and as described in various general and more specific references that may be cited and discussed in the present specification.

[0094] Any patents, published patent applications, and non-patent publications mentioned in the specification are hereby incorporated by reference in their entirety.

[0095] All examples implementing the present disclosure can be made and executed without undue experimentation in light of the present disclosure. While particular examples have been described, it will be apparent to those of skill in the art that variations may be applied to the systems, apparatus, and/or methods and in the steps or in the sequence of steps of the methods described herein without departing from the concept, spirit, and scope of the inventive concept(s). All such similar substitutions and modifications apparent to those skilled in the art are deemed to be within the spirit, scope, and concept of the inventive concept(s) as defined by the appended claims.

[0096] The use of the term "a" or "an" in the claims and/or the specification may mean "one," as well as "one or more," "at least one," and "one or more than one." As such, the terms "a," "an," and "the," as well as all singular terms, include plural referents unless the context clearly indicates otherwise. Likewise, plural terms shall include the singular unless otherwise required by context.

[0097] The use of the term "or" in the present disclosure (including the claims) is used to mean an inclusive "and/or" unless explicitly indicated to refer to alternatives only or unless the alternatives are mutually exclusive. For example, a condition "A or B" is satisfied by any of the following: A is true (or present) and B is false (or not present), A is false (or not present) and B is true (or present), and both A and B are true (or present).

[0098] As used in this specification and claim(s), the words "comprising, "having," "including," or "containing" (and any forms thereof, such as "comprise" and "comprises," "have" and "has," "includes" and "include," or "contains" and "contain," respectively) are inclusive or open-ended and do not exclude additional, unrecited elements or method steps.

[0099] Unless otherwise explicitly stated as incompatible, or the physics or otherwise of the embodiments, examples, or claims prevent such a combination, the features of examples disclosed herein, and of the claims, may be integrated together in any suitable arrangement, especially ones where there is a beneficial effect in doing so. This is not limited to only any specified benefit, and instead may arise from an "ex post facto" benefit. This is to say that the combination of features is not limited by the described forms, particularly the form (e.g. numbering) of example(s), embodiment(s), or dependency of claim(s). Moreover, this also applies to the phrase "in one embodiment," "according to an embodiment," and the like, which are merely a stylistic form of wording and are not to be construed as limiting the following features to a separate embodiment to all other instances of the same or similar wording. This is to say, a reference to 'an,' 'one,' or 'some' embodiment(s) may be a reference to any one or more, and/or all embodiments, or combination(s) thereof, disclosed. Also, similarly, the reference to "the" embodiment may not be limited to the immediately preceding embodiment. Further, all references to one or more embodiments or examples are to be construed as non-limiting to the claims.

[0100] As shown in Fig. 1 there is provided a first embodiment of a smokeless article 10 having a pouch 12 containing a content 14. The pouch 12 is substantially rectangular. The pouch 12 is formed from a single sheet of material and is substantially filled by the content 14. The pouch 12 has a seal 16 along each of the three edges where the inner face of the

single sheet meets itself to seal the content 14 in the pouch 12.

[0101] Fig. 2 shows a second embodiment of a smokeless article 10' having a pouch 12 containing a content 14. The pouch 12 is substantially circular. The pouch 12 is formed from two opposing sheets of material and is substantially filled by the content 14. The pouch has a circumferential seal 16 along the edges where the two opposing sheets of material meet to seal the content 14 in the pouch 12.

[0102] Fig. 3 shows a third embodiment of a smokeless article 10" that, like the first embodiment, has a pouch 12 made from a single sheet of material. However, one of the three seals 16' is formed by an overlap of the inner face and the outer face of the single sheet meet to seal the content 14 in the pouch 12. The remaining two seals at opposing ends of the pouch 12 are formed where the inner face of the single sheet meets itself.

[0103] Figure 4 shows a fourth embodiment of a smokeless article 10‴ that comprises the second embodiment enclosed by outer pouch 12" having an outer content 14" positioned in the space between the inner pouch 12' and the outer pouch 12". The outer pouch 12" also has a circumferential seal 16‴ to seal the outer content 14" and inner pouch 12' in the outer pouch 12".

[0104] Use of the fourth embodiment begins when the smokeless article 10‴ is placed in the user's mouth where it is exposed to saliva. Saliva first permeates outer pouch 12" and dissolves and extracts the saliva soluble substances of outer content 14". Upon leaving the outer pouch 12", the saliva soluble substances of outer content 14" therefore provide the user with a first experience. Saliva subsequently further permeates the inner pouch 12' where it dissolves and extracts the saliva soluble substances of inner content 14'. The saliva soluble substances of inner content 14' therefore provide the user with a complimentary and secondary experience. When the extractable amount of saliva soluble substances in the inner content 14' and outer content 14" drops below perceivable levels the active lifetime of the smokeless article 10‴ has ended.

EXAMPLES

Preparation of Formulations

[0105] The example contents (OND formulations) were prepared according to the following method at the lab scale using a food processor.

1. All materials were dispensed into appropriately sized beakers using a 2 d.p. balance to determine weights.

2. Fillers, calcium lactate, sodium chloride, xylitol, sweetener, sodium carbonate and ammonium chloride are added to the food processor and mixed at full speed for 5 minutes.

3. Whilst mixing, the nicotine in water and flavouring is added over the course of 2-3 minutes.

4. The blend is mixed for a further 5 minutes, resulting in a final content (OND formulation).

[0106] The smokeless articles are then prepared by the following subsequent steps, making use of the content prepared as described above.

5. The content is filled into open or partially unformed pouches.

6. The open or partially unformed pouches are sealed and sprayed with the "water (sprayed)".

[0107] The following contents (OND formulations) 1-5 result in improved nicotine extraction and perception, as well as improved stability (i.e. shelf life) through pH control.

Content 1

[0108]

Material	%w/w	mg/pouch
Nicotine	1.44	9.10
Water	7.12	45.00
Flavouring	3.95	25.00
Filler - MCC microspheres	40.01	253.00
Filler - Wheat Fibre	11.07	70.00
Sodium Chloride	1.90	12.00
Xylitol	2.53	16.00
Ammonium Chloride	0.19	1.20
Sweetener	0.09	0.60
Sodium Carbonate	0.06	0.40
Water (Sprayed)	29.26	185.00
Calcium Lactate	2.37	15.00
Total	**100.0**	**632.30**

Content 2

[0109]

Material	%w/w	mg/pouch
Nicotine	1.43	8.90
Water	7.23	45.00
Flavouring	4.02	25.00
Filler - MCC microspheres	45.99	286.20
Filler - Wheat Fibre	3.21	20.00
Sodium Chloride	1.93	12.00
Xylitol	2.57	16.00
Ammonium Chloride	0.19	1.20
Sweetener	0.10	0.60
Sodium Carbonate	0.06	0.40
Water (Sprayed)	30.85	192.00
Calcium Lactate	2.41	15.00
Total	**100.0**	**622.30**

Content 3

[0110]

Material	%w/w	mg/pouch
Nicotine	1.44	9.10
Water	7.12	45.00
Flavouring	3.95	25.00
Filler - MCC microspheres	43.17	273.00
Filler - Wheat Fibre	7.91	50.00
Sodium Chloride	1.90	12.00
Xylitol	2.53	16.00
Ammonium Chloride	0.19	1.20
Sweetener	0.09	0.60
Sodium Carbonate	0.06	0.40
Water (Sprayed)	29.26	185.00
Calcium Lactate	2.37	15.00
Total	**100.0**	**632.30**

Content 4

[0111]

Material	%w/w	mg/pouch
Nicotine	1.42	8.80
Water	7.25	45.00
Flavouring	4.03	25.00
Filler - MCC microspheres	45.89	285.00
Filler - Wheat Fibre	3.22	20.00
Sodium Chloride	1.93	12.00
Xylitol	2.58	16.00
Ammonium Chloride	0.19	1.20
Sweetener	0.10	0.60
Sodium Carbonate	0.06	0.40
Water (Sprayed)	30.92	192.00
Calcium Lactate	2.42	15.00
Total	**100.0**	**621.00**

Content 5

[0112]

Material	%w/w	mg/pouch
Nicotine	1.44	9.10
Water	7.12	45.00
Flavouring	3.95	25.00
Filler - MCC microspheres (MCC 200 Spheres)	41.59	263.00
Filler - Wheat Fibre	9.49	60.00
Sodium Chloride	1.90	12.00
Xylitol	2.53	16.00
Ammonium Chloride	0.19	1.20
Sweetener	0.09	0.60
Sodium Carbonate	0.06	0.40
Water (Sprayed)	29.26	185.00
Calcium Lactate	2.37	15.00
Total	**100.0**	**632.30**

[0113] The following contents 6 and 7, and comparative contents 8 and 9, are used to demonstrate in Fig. 5 the pH stability of the compositions according to the claims, relative to those outside of the scope of the claims. It can be seen that the content of the present invention exhibits improved pH stability.

Content 6

[0114]

Material	%w/w	mg/pouch
Nicotine	1.41	9.30
Water	6.81	45.00
Flavouring	6.35	42.00
Filler - MCC microspheres	41.52	274.40
Filler - Alba Fibres	4.06	26.80
Sodium Chloride	3.03	20.00
Xylitol	4.09	27.00
Ammonium Chloride	0.30	2.00
Sweetener	0.15	1.00
Sodium Carbonate	0.06	0.40
Water (Sprayed)	29.20	193.00
Calcium Lactate	3.03	20.00
Total	**100.00**	**660.90**

Content 7

[0115]

Material	%w/w	mg/pouch
Nicotine	1.41	9.30
Water	6.81	45.00
Flavouring	6.35	42.00
Filler - MCC microspheres	41.52	274.40
Filler - Wheat Fibre	4.06	26.80
Sodium Chloride	3.03	20.00
Xylitol	4.09	27.00
Ammonium Chloride	0.30	2.00
Sweetener	0.15	1.00
Sodium Carbonate	0.06	0.40
Water (Sprayed)	29.20	193.00
Calcium Lactate	3.03	20.00
Total	**100.00**	**660.90**

Comparative Content 8

[0116]

Material	%w/w	mg/pouch
Nicotine	1.41	9.30
Water	6.81	45.00
Flavouring	6.35	42.00
Filler - MCC microspheres	41.07	271.50
Filler - Alba Fibres	4.58	30.30
Sodium Chloride	3.03	20.00
Xylitol	4.08	27.00
Ammonium Chloride	0.30	2.00
Sweetener	0.12	0.80
Sodium Carbonate	0.06	0.40
Water (Sprayed)	32.19	212.80
Total	**100.00**	**661.10**

Comparative Content 9

[0117]

Material	%w/w	mg/pouch
Nicotine	1.41	9.30
Water	6.81	45.00
Flavouring	6.35	42.00
Filler - MCC microspheres	52.64	348.00
Sodium Chloride	3.02	20.00
Xylitol	4.08	27.00
Ammonium Chloride	0.30	2.00
Sweetener	0.12	0.80
Sodium Carbonate	0.06	0.40
Water (Sprayed)	25.21	166.70
Total	**100.00**	**661.20**

[0118] The data plotted in Fig. 5 is set out below in Tables 1 to 4. It can be seen that the pH of Content 6 and Content 7, within the scope of the claims, does not change by more than 0.25 pH units over a period of 12 weeks. This is true whether it is the first and last time points that are compared (at 0 weeks and 12 weeks), or whether any two given time points are compared.

Table 1

	Content 6 pH	
Timepoint (weeks)	**Average**	**RSD %**
0	7.78	N/A
4	7.75	0.20
8	7.83	0.13
12	7.75	0.09
% Change (0-12)	**-0.42**	N/A

Table 2

	Content 7 pH	
Timepoint (weeks)	**Average**	**RSD %**
0	7.84	N/A
4	7.84	0.19
8	7.82	0.32
12	7.64	0.00
% Change(0-12)	**-2.38**	N/A

Table 3

	Comparative Content 8 pH	
Timepoint (weeks)	**Average**	**RDS %**
0	8.40	N/A
4	8.24	0.24
8	7.70	0.07
12	8.03	0.29
% Change (0-12)	**-4.37**	N/A

Table 4

	Comparative Content 9 pH	
Timepoint (weeks)	**Average**	**RSD %**
0	8.33	N/A
4	8.15	0.31
8	7.95	0.48
12	7.92	0.19
% Change (0-12)	**-4.92**	N/A

Claims

1. A smokeless article for oral delivery comprising a pouch enclosing a content, the content comprising a nicotinic compound, calcium lactate and sodium carbonate, wherein the pH stability of the content is such that the pH changes by less than or equal to 0.25 units over a period of 12 weeks.

2. The smokeless article according to claim 1, wherein the calcium lactate is present at 2-4 wt% relative to the total weight

of the content.

3. The smokeless article according to claim 1 or claim 2, wherein the calcium lactate is present at 2.25-3.75 wt% relative to the total weight of the content.

4. The smokeless article according to any one of claims 1 to 3, wherein the calcium lactate comprises calcium lactate pentahydrate.

5. The smokeless article according to any one of claims 1 to 4, wherein the sodium carbonate is present at up to 0.1 wt% relative to the total weight of the content.

6. The smokeless article according to claim 5, wherein sodium carbonate is present at 0.01-0.1 wt% relative to the total weight of the content.

7. The smokeless article according to any one of claims 1 to 6, wherein the the content further comprises a filler.

8. The smokeless article according to claim 7, wherein the filler comprises one or more natural fibres; and optionally wherein the one or more natural fibres comprises one or more of micro-crystalline cellulose, wheat fibre, bamboo fibre, apple fibre, citrus fibre, sugar cane fibre, rice fibre, psyllium fibre, potato fibre, pea fibre, and oat fibre

9. The smokeless article according to any one of claims 1 to 8, wherein the content further comprises a flavouring.

10. The smokeless article according to any one of claims 1 to 9, wherein the content comprises less than 5 wt% tobacco.

11. The smokeless article according to claim 10, wherein the content is free of tobacco.

12. A method of preparing a smokeless article according to any one of claims 1 to 11, comprising a blending step.

13. Use of calcium lactate in the content of the smokeless article according to any one of claims 1 to 11 to improve nicotine perception by a user.

14. A kit comprising a plurality of smokeless articles according to any one of claims 1 to 11.

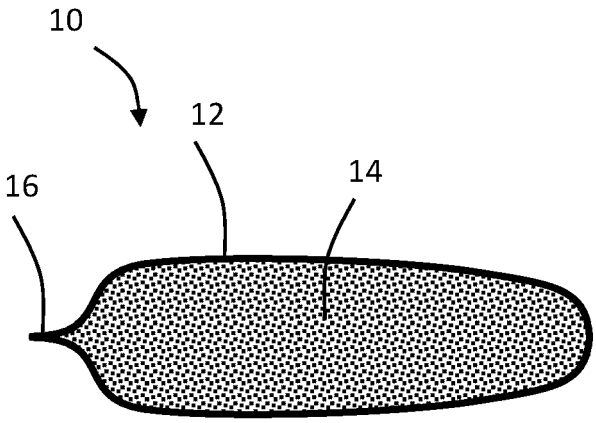

Fig. 1

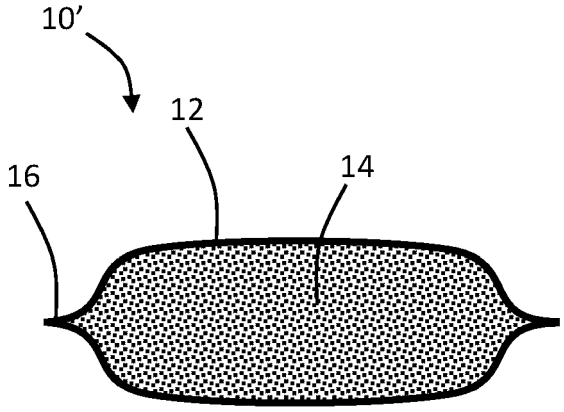

Fig. 2

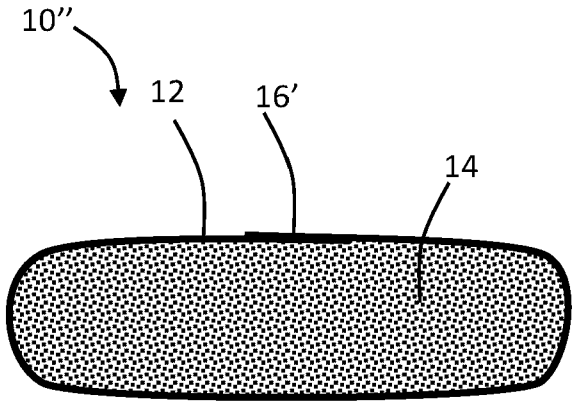

Fig. 3

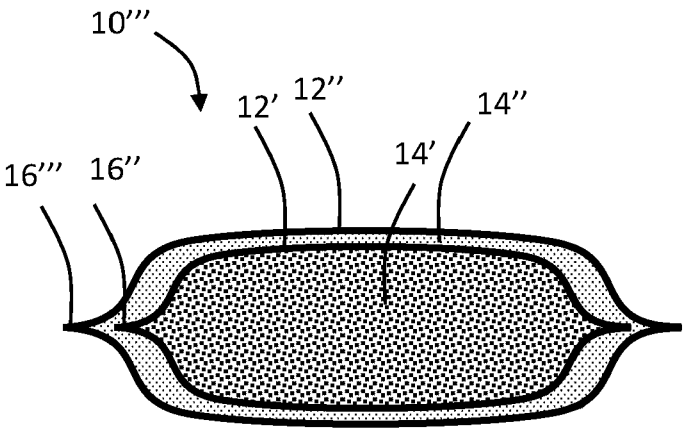

Fig. 4

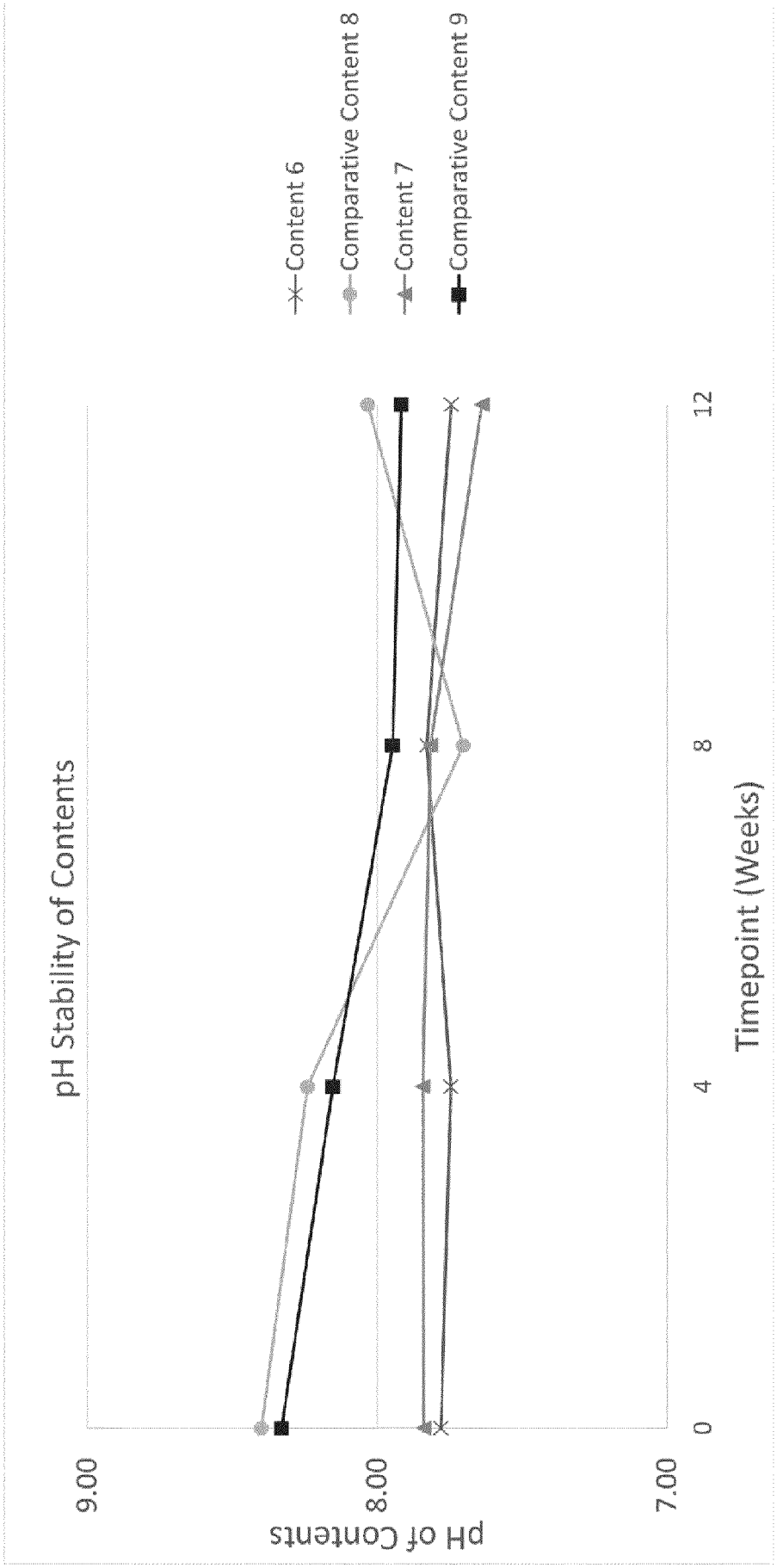
pH Stability of Contents
Content 6
Comparative Content 8
Content 7
Comparative Content 9
pH of Contents
9.00
8.00
7.00
0
4
8
12
Timepoint (Weeks)

Fig. 5

Europäisches Patentamt
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EUROPEAN SEARCH REPORT

Application Number
EP 24 21 2200

DOCUMENTS CONSIDERED TO BE RELEVANT

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X	EP 4 000 424 A1 (NCP NEXTGEN AS [DK]) 25 May 2022 (2022-05-25) * paragraph [0004] - paragraph [0013]; examples 3,5C, 5D; tables 11 (P22), 12 (P32), 6 *	1-14	INV. A24B13/00 A24B15/16 A24B15/30 A24B15/42
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X	CA 3 198 533 A1 (PHILIP MORRIS PRODUCTS SA [CH]) 19 May 2022 (2022-05-19) * examples 3, 5C, 5D; tables 11(P229, 12(P23), 6 *	1-14	
X	EP 3 917 339 B1 (SWEDISH MATCH NORTH EUROPE AB [SE]) 7 June 2023 (2023-06-07) * paragraph [0007] - paragraph [0013]; claims 1,5,6,8,9,10,17,18,19,20,21,22,23; example 1; tables 1A, 1B * * paragraph [0021] * * paragraph [0063] *	1-14	

TECHNICAL FIELDS SEARCHED (IPC)
A24B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	11 April 2025	Munteanu, I

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 24 21 2200

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