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(54) **SMOKELESS ARTICLE**

(57) The present invention relates to a smokeless article for oral delivery comprising a pouch enclosing an oral nicotine delivery (OND) formulation, the OND formulation comprising at least two 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. A method of manufacturing the article and kits comprising the article are also described.

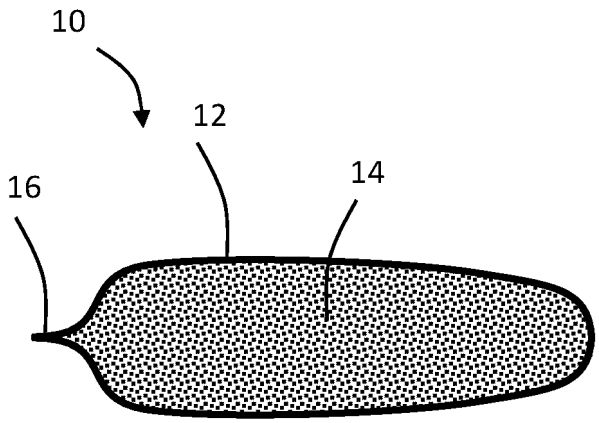

Figure 1

EP 4 740 755 A1

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 nicotine for oral delivery. This disclosure also relates to methods of manufacturing 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 for improved design of smokeless articles to enhance the user experience and improve the function of its constituent components.

[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 use.

[0006] The present disclosure provides, in a first aspect, a smokeless article for oral delivery comprising a pouch enclosing a content, e.g., an oral nicotine delivery (OND) formulation.

[0007] The content comprises at least two 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.

[0008] A smokeless article comprising a content comprising at least two 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 leads to improved properties of the content and the article itself.

[0009] Without being bound by any theory, the pH of an OND formulation 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. In addition, it is preferred that the pH does not vary significantly over time before use, as this can reduce the shelf-life of a smokeless article.

[0010] 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.

[0011] The resultant content as described herein has a pH value that is well controlled and more stable over time due to the combination of the pH regulators in the content. Comparatively, smokeless articles that only contain one pH regulator may experience a drop in pH over time prior to use.

[0012] The improved stability of the pH of the content is advantageous because it ensures that the content maintains the correct pH for good nicotine absorption through the oral mucosa over time. This improves the shelf-life of the content. If the pH drops over time, then when the article is used the nicotine absorption is worse, so the shelf-life of the products is shortened.

[0013] In addition, the nicotine absorption through the oral mucosa may be improved by using the combination of at least two 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 in the content as it gives better pH control to enable optimum bioavailability and uptake of the active compound. Therefore, the user's perception of the active ingredient is improved, e.g. an improved, stronger, nicotine perception.

[0014] The term "sodium carbonate" may be used to refer to sodium bicarbonate, sodium carbonate, and mixtures thereof.

[0015] 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. In preferred embodiments herein, buffering activity is provided so "pH regulators", "buffers" and "pH stabilisers" are preferred.

[0016] In general, pH regulators, buffers, pH stabilisers, pH modifiers, and pH adjusters are provided to adjust the user experience and/or modify the bioavailability of a pharmacologically active compound. The overall pH of the smokeless

article is preferably pH 7 to pH 10, such as pH 7.5 to pH 9.5, pH 7.75 to pH 9.25, pH 8 to pH 9, or 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.

[0017] The overall pH of a smokeless article may be determined by, for example, (i) placing the smokeless article in 10 mL of distilled water (ii) agitating the mixture for at least 5 minutes and (iii) measuring the pH of the solution with a pH probe.

[0018] 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, sublingual, periodontal, gingival and ingestion.

[0019] The smokeless article may be an oral nicotine delivery (OND) article when the active agent within the content comprises a nicotinic compound.

[0020] In some examples, the active agent comprises or consists of an active compound. In some examples the active agent comprises or consists of a nicotinic compound.

[0021] The smokeless article comprises a pouch enclosing a content, wherein the content (including e.g. a nicotinic compound and non-tobacco plant material fibres) is completely enclosed by the pouch. The pouch is sealed to ensure that the contents of the pouch does not scatter inside the mouth.

[0022] The smokeless article may have a mass of about 0.1 g to 5.0 g, such as about 0.5 g to about 4.0 g or about 1.0 g to about 3.0 g.

[0023] The smokeless article may have a length of about 30 mm, such as about 28 mm or 26 mm, a width of about 12 mm, such as about 10 mm or 8 mm, and a depth of about 5 mm, such as about 4 mm or 3 mm.

[0024] The smokeless article may have an active lifetime of about 20 minutes to about 60 minutes, such as about 25 minutes to 50 minutes or 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, for an article containing an active ingredient such as nicotine or other pharmacologically active ingredient the active lifetime may be defined as the in use period of time in which 90%wt of the available pharmacologically active 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 pharmacologically active ingredient 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.

[0025] The pouch may be formed from one or more materials. The pouch material may be formed from fiber, paper, cloth and fabric. The pouch material may be formed from one or more polymeric materials. 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.

[0026] The pouch is typically completely insoluble in saliva. Suitable insoluble pouch materials include, but are not limited to, fiber, paper, water-insoluble polymers, cloth and fabric. Suitable soluble pouch materials include, but are not limited to, water-soluble polymers such as polyethylene oxide (PEO), hydroxypropyl cellulose (HPC) and hydroxypropyl methylcellulose (HPMC).

[0027] 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 (e.g. a nicotinic compound and non-tobacco plant material fibres) may be placed before completely sealing the pouch closed. The sheets may be the same thickness or different thicknesses.

[0028] 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.

[0029] 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.

[0030] In some examples, the content comprises more than 0.01 wt.% of any or each pH regulator individually, for example, above 0.02 wt.%, above 0.03 wt.%, above 0.05 wt.%, above 0.1 wt.%, above 0.5 wt.%, above 1 wt.%, or above 3 wt.%, based on the total weight of the content. Having a minimum amount of pH regulator ensures that it has an effect on the pH of the content.

[0031] In some examples, the content comprises up to 10 wt.% of any or each pH regulator individually, for example, up to 8 wt.%, up to 6 wt.%, up to 5 wt.%, up to 4 wt.%, up to 3 wt.%, up to 2 wt.%, up to 1 wt.%, or up to 0.05 wt.%, based on the total weight of the content. Having a maximum amount of pH regulator ensures that it does not make the content too alkaline, which may cause irritation to the user.

[0032] In some examples, the content comprises between 0.01 and 10 wt.% of each pH regulator individually, based on the total weight of the content.

[0033] In some examples, the content comprises a total between 0.01 and 10 wt.% of pH regulators, based on the total weight of the content.

[0034] The amount of pH regulator may be chosen to ensure there is an effect on the pH of the content, provide good conditions for nicotine absorption, and avoid causing irritation to the user.

[0035] The total amount of pH regulator may be chosen based on the combination of pH regulators to ensure that the pH is between 8 and 9.

[0036] In some examples, the content comprises more than 0.01 wt.% sodium carbonate, for example, above 0.02 wt.%, above 0.03 wt.%, above 0.04 wt.%, or above 0.05 wt.%, based on the total weight of the content. Having a minimum amount of sodium carbonate ensures that it has an effect on the pH of the content.

[0037] In some examples, the content comprises up to 1 wt.% sodium carbonate, for example, up to 0.8 wt.%, up to 0.5 wt.%, up to 0.3 wt.%, up to 0.1 wt.%, up to 0.09 wt.%, up to 0.08 wt.%, or up to 0.07 wt.%, based on the total weight of the content. Having a maximum amount of sodium carbonate ensures that it does not make the content too alkaline, which may cause irritation to the user.

[0038] In some examples, the content comprises between 0.01 and 1 wt.% sodium carbonate, for example, 0.01-0.5 wt.%, 0.01-0.3 wt.%, 0.01-0.1 wt.%, 0.03-0.1 wt.%, based on the total weight of the content.

[0039] In some examples, the content comprises 0.06 wt.% sodium carbonate, based on the total weight of the content.

[0040] The amount of sodium carbonate may be chosen to control the pH to between 8 and 9.

[0041] In some examples, the content comprises sodium carbonate in combination with one or more further pH regulators, each independently in an amount as described above.

[0042] In some examples, the content comprises between 0.01 and 1 wt.% sodium carbonate and between 0.01-10 wt.% of at least one further pH regulator, based on the total weight of the content.

[0043] In some examples the active agent comprises or consists of a nicotinic compound.

[0044] The nicotinic compound (for example, dissolved in a suitable solvent) may be added to or mixed with the pH regulators prior to incorporation into the smokeless article. For example, the nicotine compound may be added to the solution of a pH regulator, or added to a mixture containing a pH regulator and one or more further components. Alternatively, a pH regulator may be added to the solution of nicotinic compound, or added to a mixture containing the nicotinic compound and one or more further components.

[0045] The nicotinic compound may be selected from nicotine, nicotine salt(s), nicotine complex(es); and nicotine solvate(s).

[0046] In some examples, the smokeless article is tobacco free. In this way, the user may experience a similar or enhanced recreational/pharmaceutical effect as compared to conventional tobacco-containing products without the presence of tobacco and, e.g. without tobacco flavour.

[0047] In some examples, the content comprises a nicotinic compound, water, and at least two 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. In some examples, the content comprises a nicotinic compound, water, a flavourant, and at least two 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.

[0048] In some examples, the content comprises a nicotinic compound (e.g. nicotine) in an amount of from 0.3 wt.% to 2 wt.%, for example 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.

[0049] In some examples, the total nicotinic compound (e.g. nicotine) content per pouch is from 4 to 15 mg. In some examples, the nicotinic compound content per pouch is about 7-10 mg, for example the nicotinic compound content per pouch is about 8 mg.

[0050] In some examples, the amount of water in the content is from 30 wt.% to 60 wt.%, for example from 35 wt.% to 60 wt.%, from 40 wt.% to 60 wt.%, from 40 wt.% to 55 wt.%, from 40 wt.% to 50 wt.%, or from 42 wt.% to 50 wt.% based on the total weight of the content. In some examples, the amount of water in the content is from 42 wt.% to 48 wt.%, based on the total weight of the content.

[0051] As explained above, the use of particular combinations of pH regulators allows for better control of the pH of the content, so that nicotine absorption through the oral mucosa is improved, the pH is more stable over time, and the shelf-life of the content is improved. Preferably the pH is buffered to the desired range.

[0052] In some examples, the content (e.g., OND formulation) has a pH of 8-9.

[0053] In some examples, the content (e.g., OND formulation) maintains a stable pH for at least 4 months, at least 5 months, at least 6 months, at least 7 months, or at least 8 months.

[0054] In some examples, the content (e.g., OND formulation) has a shelf-life of at least 4 months, at least 5 months, at least 6 months, at least 7 months, or at least 8 months.

[0055] In some examples, the content comprises a nicotinic compound, at least two 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, and may comprise one or more additional substances.

[0056] In some examples, the content comprises plant fibres, a nicotinic compound, water and at least two 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, and may comprise one or more additional substances.

[0057] The or each additional substance may individually be a biologically/pharmacologically active compound, one or more types of cellulose, humectants, flavourants, fillers, preservatives, aqueous/non-aqueous solvents and binders. The or each additional substance may be provided for more than one purpose.

[0058] The contents of the pouch (i.e. the ingredients, material and/or substances enclosed within the pouch) preferably occupies substantially all of the internal volume of the pouch. The contents may occupy 80%, 85%, 90%, 95% or 100% of the internal volume of the pouch. The contents may comprise a solid material to provide physical integrity, such as an organic material (e.g. plant material) or an inorganic material. Such solid materials may naturally or inherently contain one or more biologically/pharmacologically active compounds and/or additives.

[0059] **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.

[0060] In some embodiments the contents include an active compound comprising nicotine and wherein the form of nicotine is selected from the group consisting of nicotine salts, nicotine base, stabilized nicotine and mixtures thereof. For example, the contents may include at least one nicotine salt 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.

[0061] **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 contents). 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 content is 5 to 10 wt.% of the contents e.g. around 6 to 9 wt.%.

[0062] **Flavourants** may be provided in solid or liquid form. Suitable flavourants 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 flavourant may be evenly dispersed throughout the contents or may be provided in isolated locations and/or varying concentrations throughout the contents.

[0063] As used herein, the term "flavourant" denotes a compound having a desirable taste, aroma or both.

[0064] In some examples, the content comprises one or more flavourants (e.g. peppermint flavour) in an amount of from above 0 wt.% to 10 wt.%, for example 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. 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] **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.

[0067] The humectant may have a lower limit of at least 1 % by weight of the contents such as at least 2 wt.%, such as at least 5 wt.%, such as at least 10 wt.%, such as at least 20 wt.%, such as at least 30 wt.%, or such as least 40 wt.%.

[0068] The humectant may have an upper limit of at most 70% by weight of the contents, such as at most 65 wt.%, such as at most 60 wt.%, or such as at most 20 wt.%, such as at most 10 wt %, such as at most 5 wt %, such as at most 2 wt.%.

[0069] Preferably, the amount of humectant is 1 to 70 wt.% of the contents, such as 10 to 60 wt.% or 50 to 60 wt.%.

[0070] Preferably, the contents has an overall amount of water of between 5 and 60 wt.% based on the weight of the contents such as between 40 to 60 wt.% or 50 to 60 wt.%, for example 52 to 60 wt.%.

[0071] Smokeless articles having a total moisture content of 10% or less are generally considered to be 'dry'. Smokeless articles having a total moisture content of 40% or more are generally considered to be 'wet'.

[0072] The humectant in the OND formulation may comprise or consist of water and one or more polyhydric alcohols, for example water and glycerol.

[0073] **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 or a mixture thereof.

[0074] In some examples, the content comprises a sweetener (e.g. acesulfame K) in an amount of from 0 wt.% to 1 wt.%, for example from 0.01 wt.% to 1 wt.%, from 0.01 wt.% to 0.5 wt.%, from 0.01 wt.% to 0.2 wt.%, from 0.01 wt.% to 0.1 wt.%, from 0.05 wt.% to 0.2 wt.%, or from 0.05 wt.% to 0.15 wt.% based on the total weight of the content.

[0075] The sweetener may have a lower limit of at least 0.01 % by weight of the contents such as at least 0.02 wt.%, such as at least 0.03 wt.%, such as at least 0.04 wt.%, such as at least 0.05 wt.%, or such as least 0.06 wt.%.

[0076] **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.

[0077] **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. In some embodiments the binder content is 5 to 10 wt.% of the contents, e.g. around 6 to 9 wt.% or 7 to 8 wt.%.

[0078] **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%.

[0079] **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, flavourants, pH stabilisers etc. The plant material may comprise 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.

[0080] In some examples, the plant material comprises or consist of one or more of wheat fibres, cellulose fibres, bamboo fibres, pine fibres and eucalyptus fibres.

[0081] In some examples, the plant material is bamboo fibres. The bamboo fibres may have a particle size of 10-500 μm, for example 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. In some embodiments, the bamboo fibres have a particle size of about 30 μm.

[0082] In some embodiments, the bamboo fibres have a particle size of 15-500 μm, for example, 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. In some embodiments, the bamboo fibres have a particle size of about 300 μm.

[0083] In some embodiments, the bamboo fibres have a particle size of 30-300 μm.

[0084] In some embodiments, the bamboo fibres are nicotine-dosed bamboo fibres.

[0085] As used herein, the term "particle size" when referring to fibres such as bamboo fibres indicates 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.

[0086] 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.

[0087] As used herein, the term "bamboo fibres" refers to natural fibres from plants of the Bambusoideae subfamily of the Poaceae family of grasses. The fibres may originate from any part of the plant, but in some embodiments may be originate from the stem of the plant. The fibres may be obtained from commercial sources such as JELUCEL® BF fibres sold by Jelu-werk, or may be prepared by grinding or milling plant material until fibers of the required particle size are obtained.

[0088] As used herein, the term "nicotine-dosed bamboo fibres" refers to a composition comprising bamboo fibres and a nicotinic compound. The nicotinic compound may be added to or mixed with the bamboo fibres prior to incorporation into the smokeless article. In some embodiments, the bamboo fibres are loaded into a suitable dryer, sprayed with a solution of nicotinic compound and dried to form nicotine-dosed bamboo fibres. The dryer may be a fluidised bed dryer. The solution may be a solution of nicotinic compound in glycerin. In some embodiments, the solution of nicotinic compound in glycerin may comprise from 10 to 50 wt.% nicotinic compound based on the total solution weight, for example from 10 to 40 wt.% or from 10 to 30 wt.%.

[0089] In some examples, the content comprises sodium carbonate, and at least one further pH regulator selected from the list of sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate.

[0090] In some examples the content comprises sodium carbonate, and at least one further pH regulator selected from the list of sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia and calcium carbonate.

[0091] Use of sodium carbonate in smokeless articles is known but combining a second pH regulator selected from the list provides advantages as discussed previously. The pH control is improved, particularly over time. Therefore, shelf-life is improved as well as nicotine absorption properties. Particularly good nicotine absorption properties and shelf-life may be achieved using sodium carbonate as one of the pH regulators, whilst only requiring a small amount.

[0092] In some examples the content comprises calcium lactate as a pH regulator.

[0093] In some examples the content comprises sodium phosphate dibasic as a pH regulator.

[0094] In some examples the content comprises sodium citrate as a pH regulator.

[0095] In some examples the content comprises meglumine as a pH regulator.

[0096] In some examples the content comprises ammonia as a pH regulator.

[0097] In some examples the content comprises calcium carbonate as a pH regulator.

[0098] In some examples, the content comprises sodium carbonate and calcium lactate. Advantageously, the use of calcium lactate in this combination may provide particularly good nicotine absorption properties.

[0099] In some examples, the content comprises sodium carbonate and sodium phosphate dibasic.

[0100] In some examples, the content comprises sodium carbonate and sodium hydroxide.

[0101] In some examples, the content comprises sodium carbonate and sodium citrate.

[0102] In some examples, the content comprises sodium carbonate and meglumine.

[0103] These combinations may show particularly good pH stability, nicotine absorption and/or extended shelf-life.

[0104] In some examples, the smokeless article comprises less than 5 wt.% tobacco, based on the total weight of the content. In some examples, the smokeless article is free of tobacco. The combination of pH regulators may be chosen to provide the best pH control for non-tobacco pouches. The presence of tobacco may affect the considerations relating to shelf-life and nicotine absorption so for some properties, behaviour relating to non-tobacco formulations may differ from that for formulations containing tobacco, or containing tobacco at a level greater than 5 wt.%.

[0105] A second aspect of the invention is the use of the combination of at least two 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 in the content of a smokeless article, to improve nicotine absorption through the oral mucosa and improve product shelf-life.

[0106] A third aspect of the invention is a process of manufacturing the smokeless article according to the first aspect, comprising the steps of:

(i) forming one or more sheets of pouch material around the contents; and,

(ii) thermally or chemically sealing the pouch material to enclose the contents.

[0107] A fourth aspect of the invention is a kit comprising a plurality of smokeless articles according to the first aspect and a container.

[0108] The skilled person will appreciate that except where mutually exclusive, a feature or parameter described in relation to any one of the above aspects may be applied to any other aspect. Furthermore, except where mutually exclusive, any feature or parameter described herein may be applied to any aspect and/or combined with any other feature or parameter described herein.

[0109] 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

[0110]

Figure 1 shows a cross sectional view of a first embodiment of a smokeless article.
Figure 2 shows a cross sectional view of a second embodiment of a smokeless article.
Figure 3 shows a cross sectional view of a third embodiment of a smokeless article.
Figure 4 shows a cross sectional view of a fourth embodiment of a smokeless article.

DETAILED DESCRIPTION OF EMBODIMENTS

[0111] As shown in Figure 1 there is provided a first embodiment of a smokeless article 10 having a pouch 12 containing contents 14. The pouch 12 is substantially rectangular. The pouch 12 is formed from a single sheet of material and is substantially filled by the contents 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 contents 14 in the pouch 12.

[0112] Figure 2 shows a second embodiment of a smokeless article 10' having a pouch 12 containing contents 14. The pouch 12 is substantially circular. The pouch 12 is formed from two opposing sheets of material and is substantially filled by the contents 14. The pouch has a circumferential seal 16 along the edges where the two opposing sheets of material meet to seal the contents 14 in the pouch 12.

[0113] Figure 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 contents 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.

[0114] Figure 4 shows a fourth embodiment of a smokeless article 10‴ that comprises the third embodiment enclosed by outer pouch 12" having an outer contents 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 contents 14" and inner pouch 12' in the outer pouch 12".

[0115] Use of the second 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 contents 14". Upon leaving the outer pouch 12", the saliva soluble substances of outer contents 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 contents 14'. The saliva soluble substances of inner contents 14' therefore provide the user with a complimentary and secondary experience. When the extractable amount of saliva soluble substances in the inner contents 14' and outer contents 14" drops below perceivable levels the active lifetime of the smokeless article 10‴ has ended.

[0116] 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.

[0117] 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.

[0118] Any patents, published patent applications, and non-patent publications mentioned in the specification are hereby incorporated by reference in their entirety.

[0119] 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.

[0120] 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.

[0121] 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).

[0122] 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.

[0123] 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.

EXAMPLES

Preparation of formulations

[0124] The example formulations were prepared according to the following method.

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

2. All the powdered materials were added into a food processor and mixed for approximately 1-2 mins at full speed.

3. The sodium carbonate was premixed with water and gently swirled by hand for approx. 1 min.

4. The food processor was started at full speed again, then the solution prepared in step 3 above was added over the course of 2-3 mins.

5. While still mixing at high speed the flavour premix was then added over a course of 1-2 mins.

6. Finally, while the blend was still being mixed the nicotine in water was then added over the course of ~1-2 mins.

7. The sample was then removed from the food processor and stored in a silver foil pouch.

Example formulations

[0125] The example formulations contained the following components.

Formulation 1

[0126]

Material	Purpose	%w/w
Nicotine (Active premix)	Active agent	1.40
Water (Active premix)	Solvent for nicotine	12.60
Water	Solvent	29.00
Bulking agent (MCC)	Bulking agent	43.21
Calcium Lactate	pH regulator	1.00
Sodium Chloride	Flavour	1.00
Sodium Carbonate (premix)	pH regulator	0.06
Water (premix)	Solvent for sodium carbonate	0.29
Flavour	Flavour extract	10.94
Sweetener (premix)	Sweetener	0.10
Water (premix)	Solvent for sweetener	0.40
	Total	100.00

Formulation 2

[0127]

Material	Purpose	%w/w
Nicotine (Active premix)	Active agent	1.40
Water (Active premix)	Solvent for nicotine	12.60
Water	Solvent	31.04
Bulking agent (powdered cellulose)	Bulking agent	42.17
1M Sodium Hydroxide (premix)	pH regulator	0.04
Water (premix)	Solvent for sodium hydroxide	0.96
Sodium Carbonate (premix)	pH regulator	0.06
Water (premix)	Solvent for sodium carbonate	0.29
Flavour	Flavour extract	10.94
Sweetener (premix)	Sweetener	0.10
Water (premix)	Solvent for sweetener	0.40
	Total	100.00

Formulation 3

[0128]

Material	Purpose	%w/w
Nicotine (Active premix)	Active agent	1.40
Water (Active premix)	Solvent for nicotine	12.60
Water	Solvent	32.00

(continued)

Material	Purpose	%w/w
Bulking agent (powdered cellulose)	Bulking agent	41.21
Sodium Phosphate Dibasic	pH regulator	1.00
Sodium Carbonate (premix)	pH regulator	0.06
Water (premix)	Solvent for sodium carbonate	0.29
Flavour	Flavour extract	10.94
Sweetener (premix)	Sweetener	0.10
Water (premix)	Solvent for Acesulfame K	0.40
	Total	100.00

Comparative examples

[0129] For comparison, known OND formulations using a single pH regulator, sodium carbonate, have shown a decline in pH over time. The formulations below all had a pH of 8-9 when "freshly made", i.e., within 24 hours of preparation. The data below is all for formulations from the same batch with a flavourant included at 1.20 wt.%, based on the total weight of the content.

Comparative example 1

[0130] Storage at 5 °C.

Timepoint	pH result
4 weeks	6.31
8 weeks	6.11
12 weeks	6.35
24 weeks	6.85
32 weeks	6.71

Comparative example 2

[0131] Storage at 25 °C, 60% relative humidity.

Timepoint	pH result
4 weeks	6.07
8 weeks	5.94
12 weeks	5.79
24 weeks	5.92
32 weeks	5.79

Comparative example 3

[0132] Storage at 40 °C, 75% relative humidity.

Timepoint	pH result
4 weeks	5.5

(continued)

Timepoint	pH result
8 weeks	5.43
12 weeks	5.37

[0133] Embodiments of the present invention typically display greater pH stability than those using a single pH regulator.

Claims

1. A smokeless article for oral delivery comprising a pouch enclosing a content, the content comprising at least two pH regulators selected from the list consisting of sodium carbonate, sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate.

2. A smokeless article according to claim 1, wherein the content comprises sodium carbonate and at least one further pH regulator selected from the list consisting of sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate.

3. A smokeless article according to claim 1 or 2, wherein the content comprises between 0.01 and 1 wt.% sodium carbonate.

4. A smokeless article according to any one of claims 1 to 3, wherein any pH regulator selected from the list consisting of sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate is independently present in the content in an amount between 0.01 and 10 wt.%, based on the total weight of the content, such that the content has a pH of between 8 and 9.

5. A smokeless article according to any one of the preceding claims, wherein the content comprises sodium carbonate and calcium lactate.

6. A smokeless article according to any one of claims 1 to 4, wherein the content comprises sodium carbonate and sodium phosphate dibasic.

7. A smokeless article according to any one of claims 1 to 4, wherein the content comprises sodium carbonate and sodium hydroxide.

8. A smokeless article according to any one of claims 1 to 4, wherein the content comprises sodium carbonate and sodium citrate.

9. A smokeless article according to any one of claims 1 to 4, wherein the content comprises sodium carbonate and meglumine.

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

11. The smokeless article according to claim 10, which is free of tobacco.

12. The smokeless article according to any one of the preceding claims, wherein the content comprises an active agent which comprises or consists of a nicotinic compound.

13. The use of sodium carbonate and at least one further pH regulator selected from the list consisting of sodium hydroxide, calcium lactate, sodium phosphate dibasic, sodium citrate, meglumine, ammonia, ammonium carbonate, and calcium carbonate, in a smokeless article for oral delivery to improve nicotine absorption through the oral mucosa, and/or improve pH stability, and/or improve shelf life; optionally wherein the smokeless article is according to any one of claims 1 to 12.

14. A method of manufacturing a smokeless article according to any one of claims 1 to 12 comprising the steps of:

(i) forming one or more sheets of pouch material around the contents; and,
(ii) thermally or chemically sealing the pouch material to enclose the contents.

15. A kit comprising a plurality of smokeless articles according to any one of claims 1 to 12 and a container.

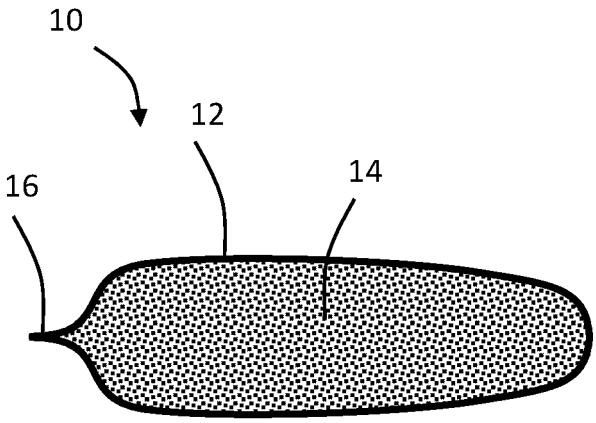

Figure 1

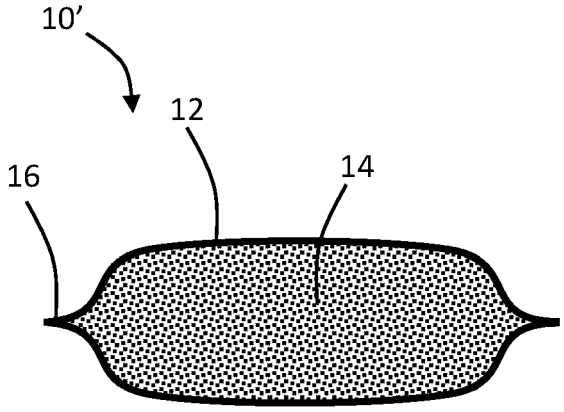

Figure 2

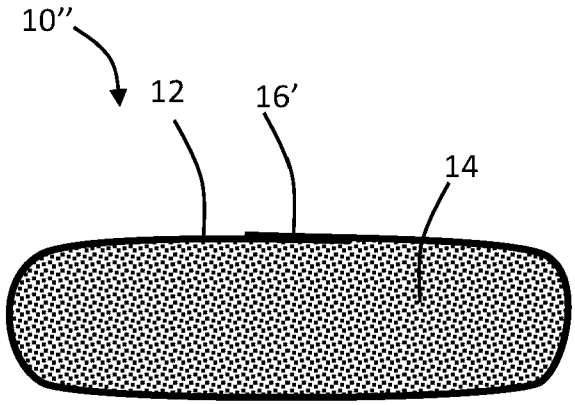

Figure 3

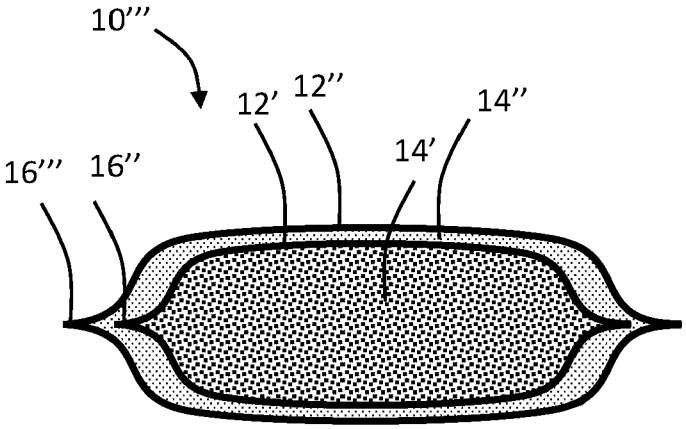

Figure 4

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EUROPEAN SEARCH REPORT

Application Number
EP 24 21 2197

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-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	14 April 2025	Munteanu, I

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EUROPEAN SEARCH REPORT

Application Number
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X	EP 3 917 339 B1 (SWEDISH MATCH NORTH EUROPE AB [SE]) 7 June 2023 (2023-06-07) * paragraph [0007] - paragraph [0008]; claim 1; figure 1; example 1; table 1B * -----	1-5, 10-15	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	14 April 2025	Munteanu, I

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