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(54) **SMOKELESS ARTICLE**

(57) A smokeless article is described including a pouch enclosing a content. The content contains powdered cellulose and an active agent and/or flavourant, wherein the powdered cellulose has an average particle size of 100-500 μm. The smokeless article may be used for oral delivery of active agent and/or flavourant to a user. Methods of manufacturing the article, kits and uses are also described.

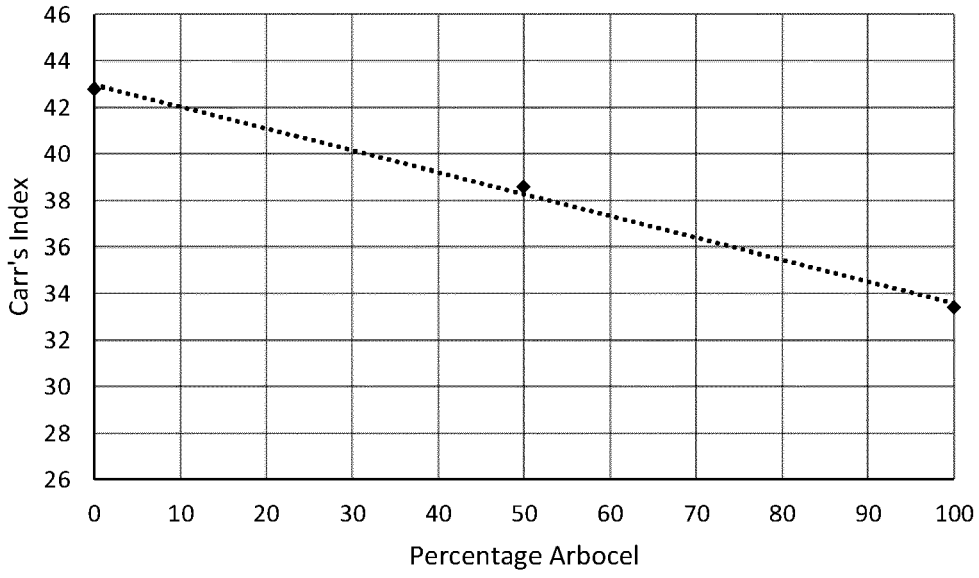

Figure 6

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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 consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and a nicotinic compound, wherein the powdered cellulose has an average particle size of 100-500 μm. The disclosure also relates to the use of a content, the content comprising powdered cellulose and a nicotinic compound.

BACKGROUND

[0002] Smokeless articles are a suitable alternative to conventional cigarettes because they do not require heating for substance delivery to the user. Instead, smokeless articles rely on saliva to extract soluble substances, typically nicotine and/or flavours, from tobacco contained within the smokeless article.

[0003] 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.

[0004] The above-described extraction and delivery process continues until the soluble element is depleted from the smokeless article. The smokeless article is then removed from the mouth and disposed of.

[0005] Some commercially available smokeless articles contain snuff. Snuff is smokeless tobacco made from ground or pulverised tobacco leaves. Snuff is available in dry form or wet (moist) form. Moist snuff may be referred to as snus. Two common varieties of snus are Scandinavian snus and American snus. Both varieties of snus are available in a loose form, but are often contained within a saliva permeable pouch.

[0006] There is a need for improved design of smokeless articles to enhance the user experience and improve the function of its constituent components.

[0007] The present disclosure has been devised in the light of the above considerations.

SUMMARY

[0008] At its most general, the present disclosure relates to a smokeless article e.g. an oral nicotine delivery (OND) article for oral use.

[0009] The present disclosure provides in a first aspect a smokeless article for oral consumption comprising a pouch enclosing a content.

[0010] In some examples, the content comprises powdered cellulose and an active agent and/or flavourant, wherein the powdered cellulose has an average particle size of 100-500 μm.

[0011] A smokeless article comprising powdered cellulose of a particle size within this range leads to improved properties of the content and the article itself. The resultant content has a lower Carr's Index (indicating improved compressibility) and a lower Hausner's Ratio (indicating improved flowability) than contents prepared with powdered cellulose having an average particle size outside this range.

[0012] The improved flowability and/or compressibility of the content is itself advantageous because it improves the handling of the powder during manufacture.

[0013] In addition, since the powder has improved compressibility and/or flowability, it is possible to increase the amount of water in the content beyond what would normally be possible, while still maintaining acceptable compressibility and flowability. As a result, when a higher water content is used, the user's perception of the active agent and/or flavourant can be improved, because a higher water content causes the perceived active agent content or flavourant content of the smokeless article to be increased. The end result is a smokeless article which seems "stronger" to the user, which is desirable to many users.

[0014] Aside from this, the powdered cellulose within this particle size range improves the mouth feel of the smokeless article which has a positive impact on the consumer's experience.

[0015] The presence of powdered cellulose with an average particle size of 100-500 μm therefore delivers a smokeless article which is easier to manufacture due to improved compressibility and/or flowability of the constituent content, which may deliver a more intense experience to the user, and which also improves mouth feel.

[0016] As used herein, the term "oral consumption" 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.

[0017] The smokeless article may be an oral nicotine delivery (OND) article when the active agent within the content comprises a nicotinic compound.

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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).

[0025] 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.

[0026] 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.

[0027] 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.

[0028] In some examples, the powdered cellulose has an average particle size above 200 μm, for example above 250 μm, above 280 μm, above 290 μm, above 300 μm, or above 310 μm.

[0029] In some examples, the powdered cellulose has an average particle size of up to 450 μm, for example up to 400 μm, up to 350 μm, up to 340 μm, up to 330 μm, or up to 320 μm.

[0030] In some examples, the powdered cellulose has an average particle size of 150-500 μm, for example 200-500 μm, 250-500 μm, 300-500 μm, 300-450 μm, 300-400 μm, or 300-350 μm.

[0031] In some examples, the powdered cellulose has an average particle size of 250-450 μm.

[0032] In some examples, the powdered cellulose has an average particle size of about 320 μm.

[0033] In some examples, the powdered cellulose has a bulk density above about 0.20 g/mL, for example above about 0.25 g/mL, above about 0.28 g/mL, or above about 0.30 g/mL.

[0034] In some examples, the powdered cellulose has a bulk density up to about 0.48 g/mL, for example up to about 0.46 g/mL, up to about 0.44 g/mL, up to about 0.43 g/mL, or up to about 0.42 g/mL.

[0035] In some examples the powdered cellulose has a bulk density of 0.20-0.5 g/mL, 0.25-0.5 g/mL, 0.28-0.5 g/mL, 0.30-0.5 g/mL, 0.30-0.45 g/mL, or 0.30-0.42 g/mL.

[0036] In some examples, the powdered cellulose has a bulk density of 0.30-0.45 g/mL, for example 0.30-0.40 g/mL.

[0037] In some examples, the powdered cellulose has a bulk density of about 0.35 g/mL.

[0038] The bulk density may be determined according to the method in DIN EN ISO 60.

[0039] In some examples, the powdered cellulose has an average particle size of 150-500 μm and a bulk density of

0.20-0.5 g/mL, for example an average particle size of 200-500 μm and a bulk density of 0.25-0.5 g/mL, an average particle size of 250-500 μm and a bulk density of 0.25-0.5 g/mL, or an average particle size of 250-500 μm and a bulk density of 0.28-0.5 g/mL.

[0040] In some examples, the powdered cellulose has an average particle size of 250-450 μm and a bulk density of 0.30-0.45 g/mL. In some examples, the powdered cellulose has an average particle size of 250-350 μm and a bulk density of 0.30-0.40 g/mL.

[0041] In some examples, the powdered cellulose has an average particle size of about 320 μm and a bulk density of about 0.35 g/mL.

[0042] In some examples, the powdered cellulose has an angle of repose of at least 30°, for example at least 32°, at least 34° or at least 36°. In some examples, the powdered cellulose has an angle of repose of up to 48°, for example up to 46°, up to 44°, up to 42°, up to 40°, up to 38° or up to 36°. In some examples, the powdered cellulose has an angle of repose of from 30° to 48°, for example from 30° to 44°, from 30° to 40°, from 32° to 40° or from 34° to 38. Angle of repose is a measure of powder flowability and may be determined by the method in ISO 4324.

[0043] As used herein, the term 'powdered cellulose' refers to a plant-based functional filler. In some examples, the powdered cellulose comprises a mechanically-processed cellulose derivative with a fibrous structure. In some examples, the mechanically processed cellulose derivative is purified. In some examples, the powdered cellulose is mechanically-disintegrated cellulose prepared by processing α-cellulose. In some examples, the powdered cellulose comprises a purified mechanically processed cellulose derivative with a fibrous structure, which is prepared by processing α-cellulose. The powdered cellulose may be obtained from commercial sources such as ARBOCEL ® A300 or Vitacel EPG 70, each sold by JRS Fibres for Life.

[0044] In some examples, the powdered cellulose contains the amorphous regions of cellulose present in the natural cellulose before processing. In some examples, the powdered cellulose is not microcrystalline cellulose (MCC).

[0045] As used herein, the term 'average particle size' when referring to the powdered cellulose indicates the average particle size as measured by laser diffraction, for example according to ASTM D4464-15 applying the Fraunhofer Diffraction theory. The average particle size can be measured using suitable equipment such as the Malvern Mastersizer 3000. Laser diffraction measures particle size distributions by measuring the angular variation in intensity of light scattered as a laser beam passes through a dispersed particulate sample. Large particles scatter light at small angles relative to the laser beam and small particles scatter light at large angles. The angular scattering intensity data is then analysed to calculate the size of the particles responsible for creating the scattering pattern, using the Mie theory of light scattering. The particle size is reported as a volume equivalent sphere diameter.

[0046] The term 'average particle size' refers to the Dv50 (or Dv0.5), which is the median for a volume distribution.

[0047] In some examples the active agent comprises or consists of a nicotinic compound.

[0048] The nicotinic compound may be added to or mixed with the powdered cellulose prior to incorporation into the smokeless article. In some embodiments, the cellulose fibres are loaded into a suitable dryer, sprayed with a solution of nicotinic compound and dried to form nicotine-dosed cellulose fibres. The dyer may be a fluidised bed dryer. The solution may be 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%.

[0049] Alternatively, the nicotinic compound (for example, dissolved in a suitable solvent) may be mixed with the powdered cellulose. For example, the powdered cellulose may be added to the solution of nicotinic compound, or added to a mixture containing the nicotinic compound and one or more further components.

[0050] The nicotinic compound may be selected from nicotine, nicotine salt(s), nicotine complex(es); and nicotine solvate(s). Alternatively or additionally, the nicotinic compound may be present within a plant material such as tobacco. Thus, the content may comprise or consist of a mixture of powdered cellulose and tobacco.

[0051] 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 experiencing undesirable components inherent to tobacco (e.g. tobacco flavour).

[0052] In some examples, the content comprises powdered cellulose, a nicotinic compound, and water. In some examples, the content comprises powdered cellulose, a nicotinic compound, water, and a flavourant.

[0053] In some examples, the content of the smokeless article comprises at least 20 wt% powdered cellulose, for examples at least 25 wt%, at least 35 wt%, at least 40 wt%, or at least 45 wt%, based on the total weight of the content.

[0054] In some examples, the content of the smokeless article comprises from 25 wt% to 60 wt% powdered cellulose, for example from 20 wt% to 60 wt%, from 20 wt% to 55 wt%, for example from 20 wt% to 50 wt%, for example from 20 wt% to 45 wt%, for example from 25 wt% to 45 wt%, based on the total weight of the content.

[0055] In some examples, the content of the smokeless article comprises from 40 wt% to 60 wt% powdered cellulose, for example from 40 wt% to 55 wt%, from 40 wt% to 50 wt% or from 40 wt% to 45 wt%, based on the total weight of the content.

[0056] In some examples, the content comprises nicotinic compound (e.g. nicotine) in an amount of from 0.3 wt% to 1 wt%, for example from 0.4 wt% to 1 wt%, from 0.5 wt% to 1 wt%, from 0.5 wt% to 0.9 wt%, from 0.5 wt% to 0.8 wt%, or from

0.3 wt% to 0.8 wt% based on the total weight of the content.

[0057] In some examples, the total nicotinic compound (e.g. nicotine) content is from 4 to 15 mg. In some examples, the nicotinic compound content is about 10 mg.

[0058] 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 45 wt% to 50 wt% based on the total weight of the content. In some examples, the amount of water in the content is from 45 wt% to 48 wt%, based on the total weight of the content.

[0059] As explained above, the use of powdered cellulose with an average particle size of 100-500 μm allows the amount of water in the content to be increased without detrimentally impacting powder flow or compressibility, thereby improving nicotine perception for the user. The content may comprise powdered cellulose, a nicotinic compound, and at least 45 wt% water, based on the total weight of the content, for example at least 46 wt%, at least 47 wt%, at least 48 wt%, at least 49 wt%, at least 50 wt%, at least 51 wt% or at least 52 wt%. Such high water content has not been previously possible without detrimental effects on other properties of the formulation such as powder flow and compressibility.

[0060] In some examples, the content has a Carr's Index of less than 42, for example less than 41, less than 40, less than 39, less than 37, less than 36, less than 35, less than 34, less than 33, less than 32, less than 31, or less than 30.

[0061] In some examples, the content has a Carr's Index of from 25 to 42, for example 29 to 42, 30 to 42, 30 to 40, 30 to 39 or 33 to 39.

[0062] Carr's Index may be determined by calculating both the tapped and bulk density of the content, e.g. using the method in Ph. Eur. 2.9.34. Carr's Index is then given by:

$$Carr's\ Index = 100 - \frac{(Tapped\ Density - Bulk\ Density)}{Tapped\ Density}$$

[0063] In some examples, the content has a Hausner's ratio of less than 1.75, for example less than 1.72, less than 1.70, less than 1.65, less than 1.64, less than 1.60, less than 1.55, less than 1.50, less than 1.45, less than 1.40, or less than 1.35.

[0064] In some examples, the content has a Hausner's ratio of from 1.35 to 1.74, for example 1.38 to 1.74, 1.40 to 1.74, 1.40 to 1.70, 1.45 to 1.70, 1.45 to 1.65 or 1.50 to 1.65.

[0065] Hausner's ratio may be determined by calculating both the tapped and bulk density of the content, e.g. using the method in Ph. Eur. 2.9.34. Hausner's ratio is then given by:

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

[0066] In some examples, the content has a Carr's Index of less than 42, for example less than 41, less than 40, less than 39, less than 37, less than 36, less than 35, less than 34, less than 33, less than 32, less than 31, or less than 30; and a Hausner's ratio of less than 1.75, for example less than 1.72, less than 1.70, less than 1.65, less than 1.64, less than 1.60, less than 1.55, less than 1.50, less than 1.45, less than 1.40, or less than 1.35. In some examples, the content has a Carr's Index of less than 40; and a Hausner's ratio of less than 1.65.

[0067] In some examples, the content has a bulk density above about 0.20 g/mL, for example above about 0.21 g/mL, above about 0.22 g/mL, or above about 0.24 g/mL.

[0068] In some examples, the content has a bulk density up to about 0.40 g/mL, for example up to about 0.38 g/mL, up to about 0.36 g/mL, up to about 0.34 g/mL, or up to about 0.338 g/mL.

[0069] In some examples the content has a bulk density of 0.20-0.40 g/mL, 0.24-0.40 g/mL, 0.24-0.38 g/mL, 0.24-0.36 g/mL, 0.24-0.34 g/mL, or 0.242-0.337 g/mL.

[0070] In some examples, the content has a tapped density above about 0.35 g/mL, for example above about 0.36 g/mL, above about 0.38 g/mL, or above about 0.39 g/mL.

[0071] In some examples, the content has a tapped density up to about 0.60 g/mL, for example up to about 0.58 g/mL, up to about 0.56 g/mL, up to about 0.54 g/mL, or up to about 0.51 g/mL.

[0072] In some examples the content has a tapped density of 0.35-0.60 g/mL, 0.36-0.58 g/mL, 0.38-0.55 g/mL, 0.38-0.52 g/mL, 0.39-0.51 g/mL, or 0.394-0.505 g/mL.

[0073] In some examples, the content has a Carr's Index of less than 40, a Hausner's ratio of less than 1.65 and a bulk density of 0.20-0.40 g/mL. In some examples, the content has a Carr's Index of less than 40, a Hausner's ratio of less than 1.65, a bulk density of 0.20-0.40 g/mL and a tapped density of 0.35-0.60 g/mL.

[0074] Tapped density can be measured using the method described in the Examples.

[0075] In some examples, the content comprises powdered cellulose, a nicotinic compound, and may comprise one or more additional substances.

[0076] In some examples, the content comprises powdered cellulose, a nicotinic compound, water and may comprise

one or more additional substances.

[0077] The or each additional substance may individually be a biologically/pharmacologically active compound, one or more types of cellulose, pH stabilisers or adjusters, humectants, flavourants, fillers, preservatives, aqueous/non-aqueous solvents and binders. The or each additional substance may be provided for more than one purpose.

[0078] 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.

[0079] **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.

[0080] 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.

[0081] **One or more types of cellulose** can be selected from microcrystalline cellulose (MCC), methyl cellulose (MC), ethyl cellulose (EC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC) and carboxymethyl cellulose (CMC). In some embodiments, the contents comprise the powdered cellulose, a nicotinic compound, and microcrystalline cellulose. MCC is particularly effective when it comes to reducing the rate of nicotine release from the pouch during use. Suitable MCC for use in the invention includes Avicel® PH-102 available from DuPont.

[0082] In some examples, the one or more types of cellulose is microcrystalline cellulose (MCC). As used herein, the term microcrystalline cellulose is a purified, partially depolymerised cellulose prepared by treating α-cellulose, obtained as a pulp from strains of fibrous plant material. Suitable types of MCC are know to the skilled person.

[0083] In some examples, the one or more types of cellulose are in the form of particles having a D_{50} particle size of at least 30 μm, for examples at least 40 μm, at least 50 μm, at least 60 μm, at least 70 μm, at least 80 μm, at least 90 μm, at least 100 μm, at least 110 μm, at least 120 μm, at least 130 μm, at least 140 μm, at least 150 μm, at least 160 μm, at least 170 μm, or at least 180 μm. In some examples, the one or more types of cellulose are in the form of particles having a D_{50} particle size of up to 500 μm, for example up to 500 μm, up to 450 μm, up to 400 μm, up to 350 μm, up to 300 μm, up to 290 μm, up to 280 μm, up to 270 μm, up to 260 μm, up to 250 μm, up to 240 μm, up to 230 μm, or up to 220 μm.

[0084] In some embodiments, the one or more types of cellulose are in the form of particles having a D_{50} particle size of from 30 to 500 μm, for examples from 100 to 500 μm or from 150 to 250 μm. In some embodiments, the one or more types of cellulose are in the form of particles having a D_{50} particle size of about 100 μm. In some embodiment, the cellulose is microcrystalline cellulose type 102 (MCC 102).

[0085] In some embodiments, the one or more types of cellulose are in the form of particles having a D_{50} particle size of about 200 μm.

[0086] In some examples, the content of the smokeless article comprises from 0 to 40 wt% one or more types of cellulose, for examples from 0 to 35 wt%, from 0 to 30 wt%, from 0 to 25 wt%, from 0 to 20 wt%, from 5 to 30 wt%, from 5 to 25 wt%, from 5 to 20 wt %, or from 10 to 20 wt% based on the total weight of the content.

[0087] In some examples, the content of the smokeless article comprises at least 5 wt% one or more types of cellulose, for examples at least 10 wt%, at least 15 wt%, at least 20 wt% based on the total weight of the content.

[0088] **pH stabilisers or adjusters** may be provided to adjust the user experience and/or modify the bicavailability of a pharmacologically active compound. For instance, under acidic conditions, nicotine is protonated and does not readily cross mucous membranes. Examples of suitable pH stabilisers include ammonia, ammonium carbonate, sodium carbonate and calcium carbonate. The overall pH of the smokeless article is preferably pH 7 to pH 9, such as pH 7.25 to pH 8.75 or pH 7.5 to pH 8.5.

[0089] 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.

[0090] In some examples, the content comprises a pH modifier (e.g. sodium carbonate) 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 0.01 wt% to 0.08 wt%, or from 0.01 wt% to 0.06 wt% based on the total weight of the content.

[0091] The pH modifier 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%.

[0092] **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%.

[0093] **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.

[0094] As used herein, the term "flavourant" denotes a compound having a desirable taste, aroma or both.

[0095] In some examples, the content comprises one or more flavourants (e.g. peppermint flavour) in an amount of from 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%, or from 2 wt% to 6 wt% based on the total weight of the content.

[0096] **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 vegetable glycerine (VG)) and their esters (e.g. glycerol mono-, di- or tri-acetate).

[0097] 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%.

[0098] The humectant may have an upper limit of at most 50% by weight of the contents, such as at most 40 wt%, such as at most 30 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%.

[0099] Preferably, the amount of humectant is 1 to 40 wt% of the contents, such as 2 to 20 wt% or 5 to 10 wt%.

[0100] 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'.

[0101] **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.

[0102] 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%, or from 0.01 wt% to 0.08 wt% based on the total weight of the content.

[0103] 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%.

[0104] **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,

[0105] 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.

[0106] **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%.

[0107] **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%.

[0108] **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.

[0109] 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.

[0110] 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.

[0111] 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.

[0112] In some embodiments, the bamboo fibres have a particle size of 30-300 μm.

[0113] In some embodiments, the bamboo fibres are nicotine-dosed bamboo fibres.

[0114] In some embodiments, the nicotine-dosed bamboo fibres comprise a nicotinic compound selected from nicotine, nicotine salts(s), nicotine complex(es), and nicotine solvate(s). In some embodiments, the nicotinic compound is provided in a plant material. In some embodiments, the plant material is tobacco.

[0115] 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.

[0116] 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.

[0117] 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.

[0118] 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%.

[0119] Any suitable parts of the tobacco plant may be used. This includes leaves, stems, roots, bark, seeds and flowers.

[0120] The tobacco may comprise one or more of leaf tobacco, stem tobacco, tobacco powder, tobacco dust, tobacco derivatives, expanded tobacco, homogenised tobacco, shredded tobacco, extruded tobacco, cut rag tobacco and/or reconstituted tobacco (e.g. slurry recon or paper recon).

[0121] The contents may comprise at least 50 wt% plant material based on the weight of the contents, e.g. at least 60 wt% plant material e.g. around 65 wt% plant material. The contents may comprise 80 wt% or less plant material e.g. 75 or 70 wt% or less plant material.

[0122] The contents may comprise a gathered sheet of homogenised (e.g. paper/slurry recon) tobacco or gathered shreds/strips formed from such a sheet.

[0123] The sheet may have a grammage greater than or equal to 100 g/m^2, e.g. greater than or equal to 110 g/m^2 such as greater than or equal to 120 g/m^2. The sheet may have a grammage of less than or equal to 300 g/m^2 e.g. less than or equal to 250 g/m^2 or less than or equal to 200 g/m^2. The sheet may have a grammage of between 120 and 190 g/m^2.

[0124] In some examples, the content comprises or consists of:

powdered cellulose, wherein the powdered cellulose has an average particle size of 100-500 μm, in an amount of from 10 wt% to 50 wt%, for example from 20 wt% to 45 wt%, based on the total weight of the content;

water, in an amount of from 40 wt% to 60 wt%, for example from 40 wt% to 50 wt%, based on the total weight of the content; and

plant fibres (e.g. bamboo fibres), in an amount of from 0 wt% to 50 wt%, for example from 10 wt% to 30 wt%, based on the total weight of the content.

[0125] In some examples, the content comprises or consists of:

powdered cellulose, wherein the powdered cellulose has an average particle size of 100-500 μm, in an amount of from 10 wt% to 50 wt%, for example from 20 wt% to 45 wt%, based on the total weight of the content;

water, in an amount of from 40 wt% to 60 wt%, for example from 40 wt% to 50 wt%, based on the total weight of the content; and

glycerine, in an amount of from 5 wt% to 20 wt%, for example from 5 wt% to 10 wt%, based on the total weight of the content.

[0126] In some examples, the content comprises or consists of:

powdered cellulose, wherein the powdered cellulose has an average particle size of 100 - 500 μm, in an amount of from 10 wt% to 50 wt%, for example from 20 wt% to 45 wt%, based on the total weight of the content;

water, in an amount of from 40 wt% to 60 wt%, for example from 40 wt% to 50 wt%, based on the total weight of the content;

glycerine, in an amount of from 5 wt% to 20 wt%, for example from 5 wt% to 10 wt%, based on the total weight of the content; and

plant fibres (e.g. bamboo fibres), in an amount of from 0 wt% to 30 wt%, for example from 10 wt% to 25 wt%, based on the total weight of the content.

[0127] A second aspect of the invention is the use of powdered cellulose having an average particle size of 100-500 μm in a smokeless article, to improve powder flow, improve mouth feel, and/or improve nicotine perception.

[0128] 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.

[0129] A fourth of the invention is a kit comprising a plurality of smokeless articles according to the first aspect and a container.

[0130] A fifth aspect of the invention is a smokeless article for oral consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and an active agent and/or flavourant; wherein the content satisfies one or more of the following:

(a) a Carr's Index of less than 42;

(b) a Hausner's ratio of less than 1.75;

(c) a bulk density of 0.20-0.40 g/mL;

(d) a tapped density of 0.35-0.60 g/mL.

[0131] In some examples, the content has a Carr's Index of less than 42, for example less than 41, less than 40, less than

39, less than 37, less than 36, less than 35, less than 34, less than 33, less than 32, less than 31, or less than 30.

[0132] In some examples, the content has a Carr's Index of from 25 to 42, for example 29 to 42, 30 to 42, 30 to 40, 30 to 39 or 33 to 39.

[0133] In some examples, the content has a Hausner's ratio of less than 1.75, for example less than 1.72, less than 1.70, less than 1.65, less than 1.64, less than 1.60, less than 1.55, less than 1.50, less than 1.45, less than 1.40, or less than 1.35.

[0134] In some examples, the content has a Hausner's ratio of from 1.35 to 1.74, for example 1.38 to 1.74, 1.40 to 1.74, 1.40 to 1.70, 1.45 to 1.70, 1.45 to 1.65 or 1.50 to 1.65.

[0135] In some examples, the content has a Carr's Index of less than 42, for example less than 41, less than 40, less than 39, less than 37, less than 36, less than 35, less than 34, less than 33, less than 32, less than 31, or less than 30; and a Hausner's ratio of less than 1.75, for example less than 1.72, less than 1.70, less than 1.65, less than 1.64, less than 1.60, less than 1.55, less than 1.50, less than 1.45, less than 1.40, or less than 1.35. In some examples, the content has a Carr's Index of less than 40; and a Hausner's ratio of less than 1.65.

[0136] In some examples, the content has a bulk density above about 0.20 g/mL, for example above about 0.21 g/mL, above about 0.22 g/mL, or above about 0.24 g/mL.

[0137] In some examples, the content has a bulk density up to about 0.40 g/mL, for example up to about 0.38 g/mL, up to about 0.36 g/mL, up to about 0.34 g/mL, or up to about 0.338 g/mL.

[0138] In some examples the content has a bulk density of 0.20-0.40 g/mL, 0.24-0.40 g/mL, 0.24-0.38 g/mL, 0.24-0.36 g/mL, 0.24-0.34 g/mL, or 0.242-0.337 g/mL.

[0139] In some examples, the content has a tapped density above about 0.35 g/mL, for example above about 0.36 g/mL, above about 0.38 g/mL, or above about 0.39 g/mL.

[0140] In some examples, the content has a tapped density up to about 0.60 g/mL, for example up to about 0.58 g/mL, up to about 0.56 g/mL, up to about 0.54 g/mL, or up to about 0.51 g/mL.

[0141] In some examples the content has a tapped density of 0.35-0.60 g/mL, 0.36-0.58 g/mL, 0.38-0.55 g/mL, 0.38-0.52 g/mL, 0.39-0.51 g/mL, or 0.394-0.505 g/mL.

[0142] In some examples, the content has a Carr's Index of less than 40, a Hausner's ratio of less than 1.65 and a bulk density of 0.20-0.40 g/mL. In some examples, the content has a Carr's Index of less than 40, a Hausner's ratio of less than 1.65, a bulk density of 0.20-0.40 g/mL and a tapped density of 0.35-0.60 g/mL.

[0143] Tapped density can be measured using the method described in the Examples.

[0144] All the options and preferences set out above in relation to the smokeless article of the fist aspect apply equally to the smokeless article of the fifth aspect, but for brevity are not repeated here.

[0145] 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.

[0146] 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

[0147] 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.

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.

Figure 5 is a plot of Hausner's Ratio against amount of powdered cellulose (Arbocel A300) for Examples 1 and 2 and Comparative Example 1.

Figure 6 is a plot of Carr's Index against amount of powdered cellulose (Arbocel A300) for Examples 1 and 2 and

Comparative Example 1.

Figure 7 is a plot of density (bulk and tapped) against amount of powdered cellulose (Arbocel A300).

DETAILED DESCRIPTION OF EMBODIMENTS

[0148] 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.

[0149] 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.

[0150] 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.

[0151] 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".

[0152] 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.

[0153] Figure 5 shows that there is a negative correlation between the percentage of powdered cellulose (Arbocel A300) used in the content, relative to the total amount of plant-based filler (powdered cellulose and bamboo fibres) and the Hausner's Ratio of the content. In other words, as the percentage of powdered cellulose is increased, the flowability of the content is improved.

[0154] Figure 6 shows that there is a negative correlation between the percentage of powdered cellulose (Arbocel A300) used in the content, relative to the total amount of plant-based filler (powdered cellulose and bamboo fibres) and the Carr's Index of the content. In other words, as the percentage of powdered cellulose is increased, the compressibility of the content is improved.

[0155] Figure 7 shows that there is a positive correlation between the percentage of powdered cellulose (Arbocel A300) used in the content, relative to the total amount of plant-based filler (powdered cellulose and bamboo fibres) and the density (both bulk and tapped) of the content. In other words, as the percentage of powdered cellulose is increased, the compressibility of the content is improved.

[0156] 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.

[0157] 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.

[0158] Any patents, published patent applications, and non-patent publications mentioned in the specification are hereby incorporated by reference in their entirety.

[0159] 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.

[0160] 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.

[0161] 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).

[0162] 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.

[0163] 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

Example 1

[0164] Example 1 was prepared containing powdered cellulose with an average particle size of 320 μm (ARBOCEL® A300). Example 1 contained the following components:

Material	Purpose	%w/w	mg/Dose	g/Batch
Nicotine	Active	0.70	4.21	**1.05**
Glycerine	Humectant	6.30	37.93	**9.45**
Water	Solvent	45.06	271.26	**67.59**
Sodium Carbonate	pH Modifier	0.06	0.37	**0.09**
Acesulfame K	Sweetener	0.08	0.48	**0.12**
BF-300	Bulking Agent (Snus Substitute)	21.90	131.84	**32.85**
Arbocel A300	Bulking Agent (Snus Substitute)	21.90	131.84	**32.85**
Peppermint flavour	Flavour Extract	4.00	24.08	**6.00**
	Total	**100.00**	**602.01**	**150.00**

[0165] Arbocel A300 is powdered cellulose supplied by Pharma Excipients. BF-300 is JELUCEL® BF-300 bamboo fibres supplied by Jelu-werk.

Example 2

[0166] Example 2 was prepared containing powdered cellulose with an average particle size of 320 μm (ARBOCEL® A300). Example 2 contained the following components:

Material	Purpose	%w/w	mg/Dose	g/Batch
Nicotine	Active	0.70	4.21	**1.05**

(continued)

Material	Purpose	%w/w	mg/Dose	g/Batch
Glycerine	Humectant	6.30	37.93	**9.45**
Water	Solvent	45.06	271.26	**67.59**
Sodium Carbonate	pH Modifier	0.06	0.37	**0.09**
Acesulfame K	Sweetener	0.08	0.48	**0.12**
BF-300	Bulking Agent (Snus Substitute)	0.00	0.00	**0.00**
Arbocel A300	Bulking Agent (Snus Substitute)	43.80	263.68	**65.70**
Peppermint flavour	Flavour Extract	4.00	24.08	**6.00**
	Total	**100.00**	**602.01**	**150.00**

Comparative Example 1

[0167] Comparative Example 1 was prepared containing no powdered cellulose (only bamboo fibres were used as bulking agent). Comparative Example 1 contained the following components:

Material	Purpose	%w/w	mg/Dose	g/Batch
Nicotine	Active	0.70	4.21	**1.05**
Glycerine	Humectant	6.30	37.93	**9.45**
Water	Solvent	45.06	271.26	**67.59**
Sodium Carbonate	pH Modifier	0.06	0.37	**0.09**
Acesulfame K	Sweetener	0.08	0.48	**0.12**
BF-300	Bulking Agent (Snus Substitute)	43.80	263.68	**65.70**
Arbocel A300	Bulking Agent (Snus Substitute)	0.00	0.00	**0.00**
Peppermint flavour	Flavour Extract	4.00	24.08	**6.00**
	Total	**100.00**	**602.01**	**150.00**

[0168] The compositions of Example 1, Example 2, and Comparative Example 1 were each prepared using the following method (Protocol A):

1. All the materials were dispensed into appropriately sized beakers using a 2 d.p. balance to determine the weights.
2. All the liquid components (Nicotine dissolved in the glycerine, Acesulfame K Solution, Sodium Carbonate solution) were added into the beaker containing the water dispensed in the previous step. This was then transferred onto a magnetic stirrer and mixed for approx. 10 mins using a magnetic stirrer bar until the solution appeared homogeneous.
3. While the above solution was mixing, the bulking agent (Arbocel and/or BF-300) was added to a Kenwood food processor, this then was mixed for ~1 min at full speed.
4. The solution prepared in step 2 was slowly added to the Kenwood food preocessor over the course of ~3-4 mins while still mixing. After this the Kenwood was stopped, opened, and the sides and bottom of the bowl were scraped.
5. The Kenwood was then restarted at full power. The peppermint flavour was added to the blend over the course of ~1-2 mins.
6. The Kenwood was then stopped again, opened, and the sides and bottom of the bowl were scraped. The Kenwood was then restarted at full power and mixed for ~1-2 mins. The Kenwood was shaken while this was happening to ensure complete mixing.
7. Finally, the blend was transferred to a foil pouch for storage.

Example 3

[0169] Carr's Index, Hausner's Ratio, bulk density and tapped density were determined for each of Examples 1-2 and Comparative Example 1, according to the following method based on Ph. Eur. 2.9.34.

1. A 100 mL Cylinder was placed on to a 2 d.p. balance, and tared.

2. Using a beaker, test powder was transferred into the 100 mL cylinder at approx. 90-degree angle until the cylinder was filled to approx. 90-100mL.

3. The volume (V0) was recorded, before tapping. The cylinder was then gently placed back on to the balance and the net weight of the contents was then recorded. The density calculated using V0 and the net weight is the bulk density.

4. The cylinder was then placed on to a JV1000 density tester, and tapped 10 times, after which the volume was recorded as (V10).

5. The cylinder was tapped another 490 times, and once again the volume was recorded as (V500).

6. This was repeated, but the cylinder was tapped a further 750 times and the volume recorded once again as (V1250).

7. If the volume of the powder in the cylinder dropped by more than 1 cm, then the cylinder was tapped a further 1250 times, this was then repeated until the volume in the cylinder dropped by no more than 1cm.

8. This whole procedure was repeated, and averages of the bulk and tapped densities were calculated.

9. The results of the above were used to calculate the Carr's index and Hasuners Ratio as per the calculations below. The lower these numbers are the better the flow of the blends is.

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

$$Carr's\ Index = 100 - \frac{(Tapped\ Density - Bulk\ Density)}{Tapped\ Density}$$

[0170] The results are provided in the Table below:

Example	*Bulk Density / g ml^{-1}*	*Tapped Density / g ml^{-1}*	*Carr's Index*	*Hausner's Ratio*
Example 1†	0.242	0.394	38.6	1.63
Example 2†	0.337	0.505	33.4	1.50
Comparative Example 1†	0.151	0.265	42.8	1.75
† Prepared at lab-scale following the method of Protocol A				

[0171] The results show that, when powdered cellulose is present in the composition, the powder properties (Carr's Index and Hausner's ratio) are improved. The same improvement is not seen when powdered cellulose is absent.

[0172] The Hausner's ratio of Examples 1 and 2 and Comparative Example 1 are plotted in Figure 5. There is a linear decrease in the Hausner's ratio as the % powdered cellulose (as a proportion of the total amount of powdered cellulose and bamboo fibres) increases. This shows that using powdered cellulose, in particular powdered cellulose having an average particle size of 100-500 μm, e.g. about 320 μm, as a bulking agent instead of other plant-based fillers such as bamboo fibres improves the powder properties.

[0173] The Carr's Index of Examples 1 and 2 and Comparative Example 1 are plotted in Figure 6. There is a linear decrease in the Carr's Index as the % powdered cellulose (as a proportion of the total amount of powdered cellulose and bamboo fibres) increases. This shows that using powdered cellulose, in particular powdered cellulose having an average particle size of 100-500 μm, e.g. about 320 μm, as a bulking agent instead of other plant-based fillers such as bamboo fibres improves the powder properties.

[0174] It would be expected that that the Carr's Index and Hausner's Ratio would decrease further when moving the production from lab-scale to factory scale. More specifically, the Carr's index can be expected to decrease by ~11 % and the Hausner's Ratio can be expected to decrease by ~8 %.

[0175] Thus when Example 2 is prepared on a factory scale the Carr's Index and Hausner's Ratio could be expected to be further improved to around 29.7 and 1.38 respectively.

[0176] Another important aspect associated with the use of powdered cellulose is the increase in density. This means that during manufacture of the product, the feedstock occupies a smaller volume, and a larger mass of fibres may be processed per unit time. This increases manufacturing capacity, reducing the overall production cost for the product and increasing efficiency of the manufacturing process.

[0177] The higher density means that the pouch may be smaller while carrying the same mass of fibre. This means that the amount of material used to manufacture the pouch per smokeless article is reduces, which reduces manufacturing cost.

[0178] Furthermore, according to test subjects, the use of powdered cellulose improved the mouth feel of the smokeless article compared to products that do not contain powdered cellulose.

Claims

1. A smokeless article for oral consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and an active agent and/or flavourant, wherein the powdered cellulose has an average particle size of 100-500 μm.

2. The smokeless article according to claim 1, wherein the powdered cellulose has an average particle size of 200-400 μm.

3. The smokeless article according to claim 1 or 2, wherein the powdered cellulose has an average particle size above 300 μm, optionally wherein the powdered cellulose has an average particle size of about 320 μm.

4. The smokeless article according to any of claims 1 to 3, wherein the powdered cellulose has a bulk density of 0.30-0.45 g/mL.

5. The smokeless article according to any one of claims 1 to 4, wherein the powdered cellulose comprises a mechanically processed cellulose derivative with a fibrous structure.

6. The smokeless article according to any one of claims 1 to 5, wherein the content comprises an active agent which comprises or consists of a nicotinic compound.

7. The smokeless article according to claim 6, wherein the nicotinic compound is selected from nicotine, nicotine salt(s), nicotine complex(es), and nicotine solvate(s); optionally wherein the nicotinic compound is provided in a plant material, optionally wherein the plant material is tobacco.

8. The smokeless article according to any one of claims 1 to 7, wherein the smokeless article is tobacco free.

9. The smokeless article according to any one of claims 1 to 8, wherein the content comprises at least 20 wt% powdered cellulose.

10. The smokeless article according to any one of claims 1 to 9, wherein the total nicotine content is from 5 to 15 mg, preferably about 10 mg.

11. The smokeless article according to any one of claims 1 to 10, wherein the content has a Carr's Index of less than 42 and/or a Hausner's Ratio of less than 1.75.

12. A smokeless article for oral consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and an active agent and/or flavourant; wherein the content satisfies one or more of the following:

    (a) a Carr's Index of less than 42;
    (b) a Hausner's ratio of less than 1.75;
    (c) a bulk density of 0.20-0.40 g/mL;
    (d) a tapped density of 0.35-0.60 g/mL.

13. The use of powdered cellulose and an active agent and/or flavourant, wherein the powdered cellulose has an average particle size of 100-500 μm, to improve powder flow, improve mouth feel, and/or improve the user's perception of the active agent and/or flavourant in a smokeless article for oral consumption; 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.

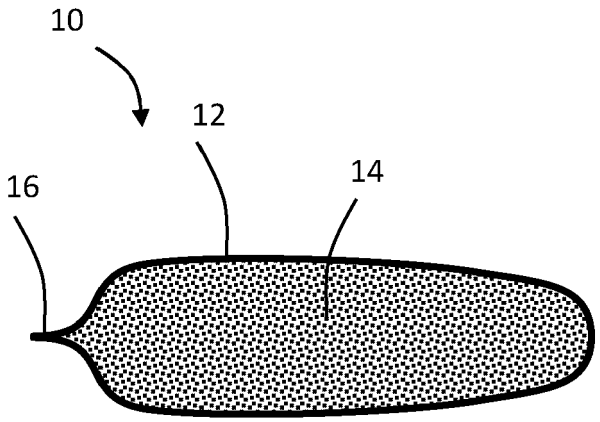

Figure 1

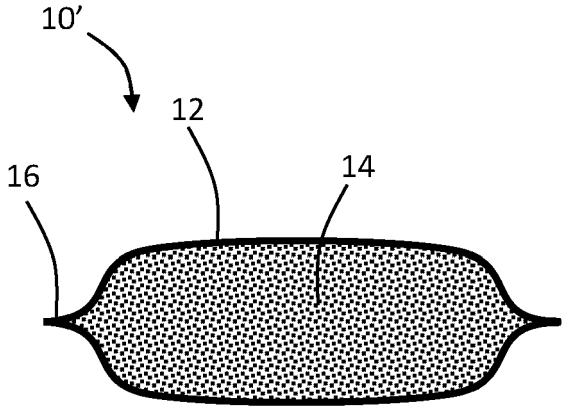

Figure 2

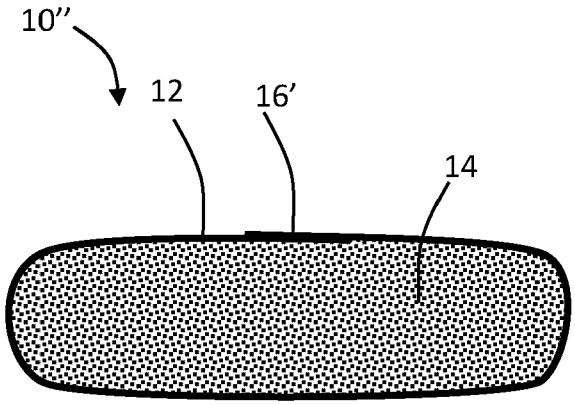

Figure 3

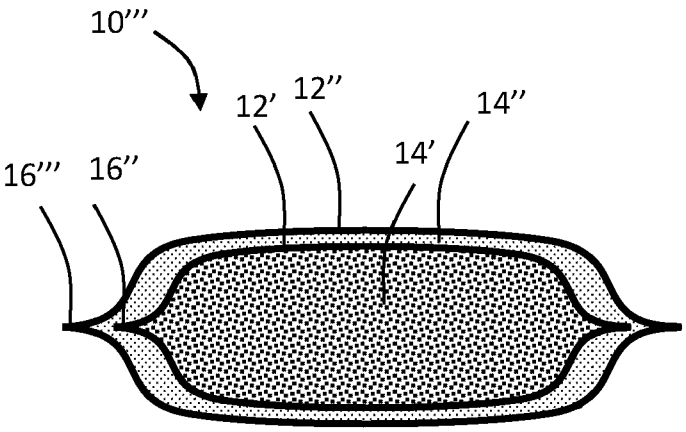

Figure 4

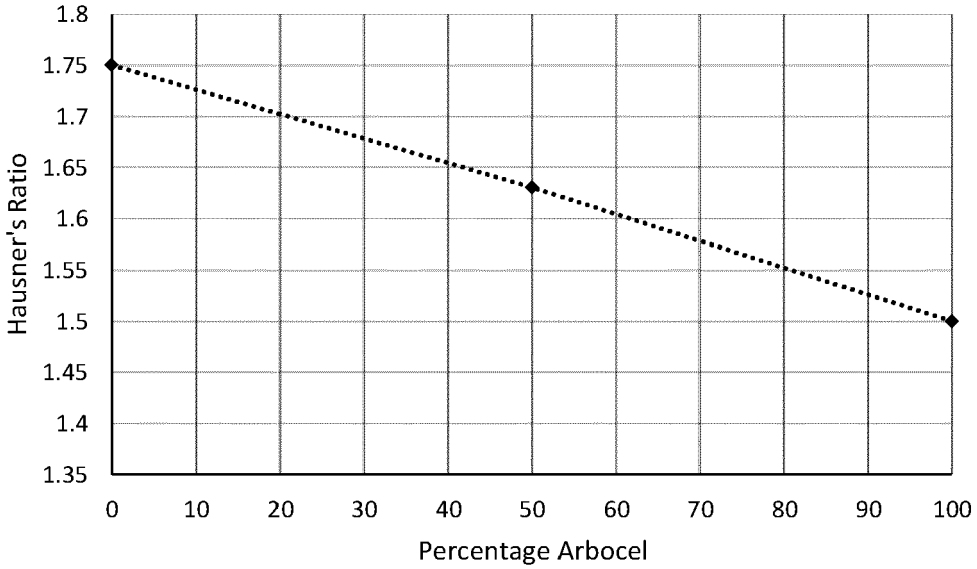

Figure 5

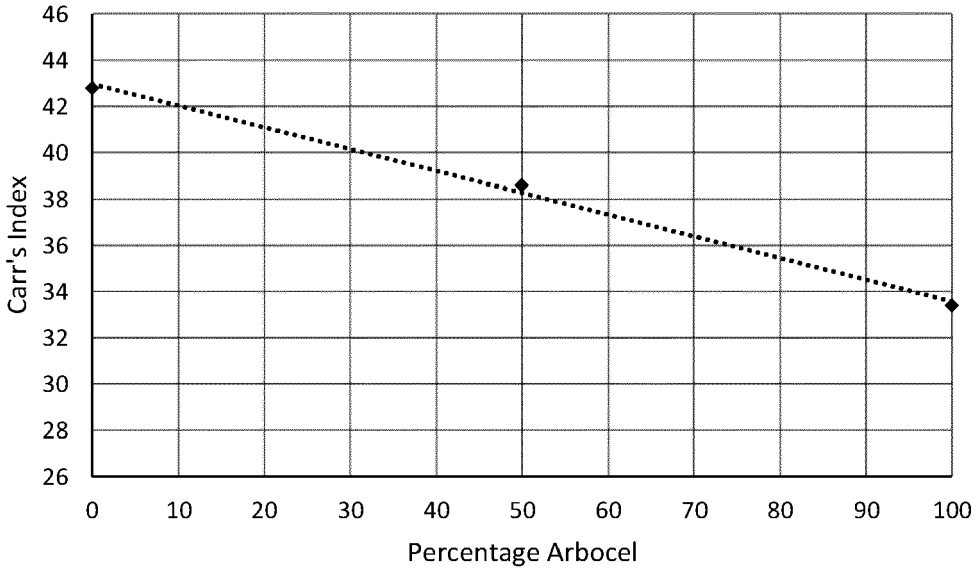

Figure 6

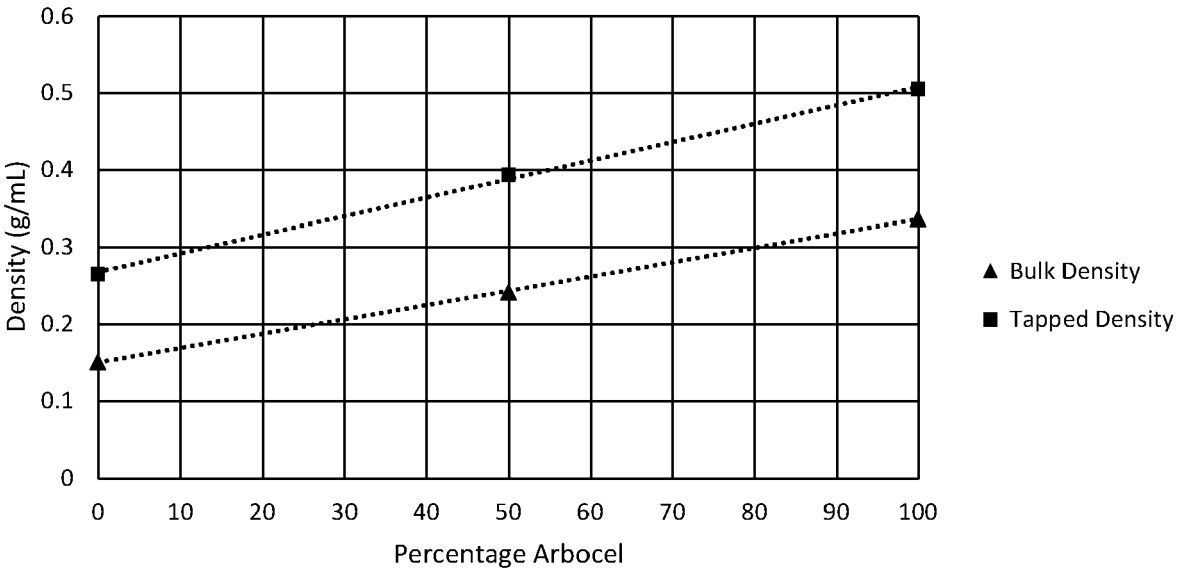
0.6
0.5
0.4
0.3
0.2
0.1
0
Density (g/mL)
0
10
20
30
40
50
60
70
80
90
100
Percentage Arbocel
Bulk Density
Tapped Density

Figure 7

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EUROPEAN SEARCH REPORT

Application Number
EP 23 19 0375

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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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
The Hague	23 April 2024	Galleiske, Anke

CATEGORY OF CITED DOCUMENTS

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EUROPEAN SEARCH REPORT

Application Number
EP 23 19 0375

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	DÜSENBERG BJÖRN ET AL: "Flowability of plant based food powders: Almond, chestnut, chickpea, coconut, hazelnut and rice", JOURNAL OF FOOD ENGINEERING, ELSEVIER, AMSTERDAM, NL, vol. 357, 5 June 2023 (2023-06-05), XP087370188, ISSN: 0260-8774, DOI: 10.1016/J.JFOODENG.2023.111606 [retrieved on 2023-06-05] * table 3 * -----	1-15	

TECHNICAL FIELDS SEARCHED (IPC)

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	23 April 2024	Galleiske, Anke

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Application Number
EP 23 19 0375

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

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LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 23 19 0375

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-11, 13(completely); 14, 15(partially)

Smokeless article for oral consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and an active agent and/or flavourant, wherein the powdered cellulose has an average particle size of 100-500 micron.

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2. claims: 12(completely); 14, 15(partially)

A smokeless article for oral consumption comprising a pouch enclosing a content, the content comprising powdered cellulose and an active agent and/or flavourant; wherein the content satisfies one or more of the following: (a) a Carr's Index of less than 42; (b) a Hausner's ratio of less than 1.75; (c) a bulk density of 0.20-0.40 g/mL; (d) a tapped density of 0.35-0.60 g/mL.

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