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(54) A POUCHED PRODUCT FOR ORAL USE COMPRISING WATER INSOLUBLE SUBSTRATE PARTICLES

(57) A pouched product for oral use comprising a liquid permeable pouch and a nicotine containing filling material enclosed by the pouch, wherein the filling material
- is a tobacco free filling material or comprises tobacco material in an amount of at most 10 % by total weight of the filling material;
- has a pre-use moisture content of from 1 % to 35 % by total weight of the filling material;
- contains nicotine in an amount of from 0.5 % to 2 % by total weight of the filling material; and
- comprises water insoluble substrate particles and one or more water-soluble components;
wherein the water insoluble substrate particles are ball-shaped particles constituting at least 65 % by dry weight of the filling material, the water insoluble substrate particles having a particle size of from 0.25 mm to 2.0 mm.

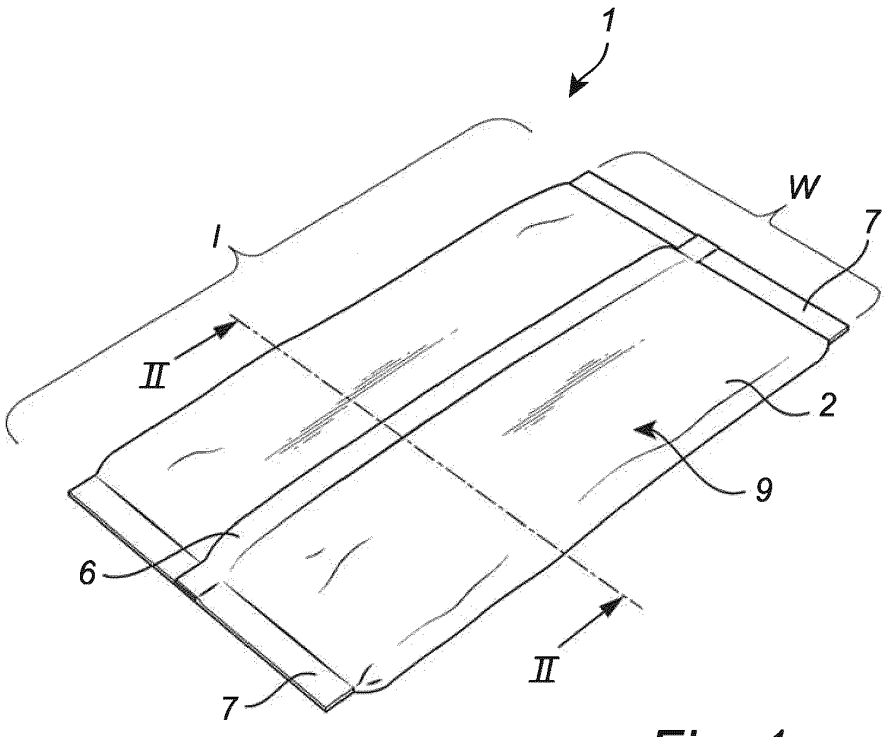

Fig. 1

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Description

TECHNICAL FIELD

[0001] The present disclosure relates to a pouched product for oral use comprising a liquid permeable pouch and a nicotine containing filling material enclosed by the pouch.

BACKGROUND

[0002] An oral pouched product as disclosed herein, is intended for use in the oral cavity, such as by buccal placement e.g., by placing the pouched product between the upper or lower gum and the lip or cheek. A pouched smokeless tobacco product may also be referred to as a portion-packed smokeless tobacco product for oral use. The pouched product is normally sized and configured to fit comfortably and discreetly in a user's mouth between the upper or lower gum and the lip or cheek.

[0003] Traditionally, oral pouched products are used in the oral cavity of a consumer to provide a user with the benefits of an active substance such as nicotine, caffeine, and/or different flavors. A common type of nicotine containing oral pouched products is oral smokeless tobacco products. Such products generally comprise water, salt, pH adjuster(s) and additional components such as flavors and humectants. Commonly, these products are called snuff.

[0004] Oral pouched nicotine containing products comprising no tobacco, or only a small amount of tobacco are now becoming increasingly popular among consumers due to inter alia their appealing appearance, freshness and taste. Moreover, this kind of product allows a user to enjoy nicotine without being exposed to tobacco. The tobacco free or almost tobacco free oral pouched products are usually flavored compositions comprising a filling material which may e.g., comprise microcrystalline cellulose or fiber material derived from plants other than tobacco.

[0005] The tobacco free oral pouched products are generally relatively dry products, with a pre-use moisture content below 3 5 % by weight of the filling material and often below 20 % by weight of the filling material. Oral pouched products having even lower moisture content, in the order of 4-15 % by weight of the filling material are also known in the art.

[0006] Oral pouched products are typically used by a consumer by placing the pouch between the upper or lower gum and the lip and retaining it there for a limited period of time, such as for 30 to 45 minutes. The product is configured to fit comfortably and discreetly in the user's mouth. The pouch material holds the filling material in place allowing saliva to pass through the pouch material to the filling material and allowing flavors and active substances such as nicotine to be leached out from the filling material and diffuse from the filling material into the consumer's mouth.

[0007] An objective with the disclosure herein is to offer an oral pouched nicotine product containing a filling material having improved nicotine release properties. A further object is to offer an oral pouched nicotine product providing improved user satisfaction. Still a further object is to offer an oral pouched nicotine product providing improved mouth feel.

SUMMARY

[0008] One or more of the above objects may be achieved with an oral pouched nicotine product according to claim 1. Variations of the disclosure are set out in the dependent claims and in the following description.

[0009] The pouched product for oral use as disclosed herein comprises a liquid permeable pouch and a nicotine containing filling material enclosed by the pouch, wherein the filling material

- is a tobacco free filling material or comprises tobacco material in an amount of at most 10 % by total weight of the filling material;
- has a pre-use moisture content of from 1 % to 35 % by total weight of the filling material;
- contains nicotine in an amount of from 0.5 % to 2 % by total weight of the filling material; and
- comprises water insoluble substrate particles and one or more water-soluble components;

wherein the water insoluble substrate particles are ball-shaped particles constituting at least 65 % by dry weight of the filling material, the water insoluble substrate particles having a particle size of from 0.25 mm to 2.0 mm.

[0010] The water insoluble substrate particles may have a particle size of from 0.3 mm to 2.0 mm, such as from 0.3 mm to 1.5 mm, such as from 0.3 mm to 1.0 mm, or from 0.25 mm to 1.0 mm.

[0011] The water insoluble substrate particles may have a particle size of from 0.25 mm to 0.6 mm, or from 0.3 mm to 0.6 mm, preferably from 0.3 mm to 0.5 mm.

[0012] Furthermore, the water insoluble substrate particles may have an aspect ratio of 0.8 or above and a sphericity of 0.8 or above.

[0013] The particle size may be determined as the d50 particle size e.g., by means of a QicPic image analysis instrument from 2012, Sympatec GmbH, ID No. 290-D, with Rodos/L dispersion line ID NO 214D and Vibri/L sample feeding ID

NO 273, or equivalent equipment.

[0014] The aspect ratio and the sphericity may be determined as the d50 aspect ratio and d50 sphericity e.g., by means of a QicPic image analysis instrument from 2012, Sympatec GmbH, ID No. 290-D, with Rodos/L dispersion line ID NO 214D and Vibri/L sample feeding ID NO 273, or equivalent equipment.

[0015] The pouched product for oral use as disclosed herein may have a nicotine release profile such that 30 % or more, preferably 40 % or more, of the nicotine in the product has been released after a use period of 10 minutes and 40 % or more, preferably 50 % or more of the nicotine in the product has been released after a use period of 30 minutes.

[0016] The water insoluble substrate particles may comprise or consist of particles of microcrystalline cellulose (MCC), water insoluble starch, silica or a mixture thereof.

[0017] It may be preferred that the water insoluble substrate particles comprise or consist of particles of microcrystalline cellulose.

[0018] The water insoluble substrate particles may constitute 65 % by dry weight to 99 % by dry weight of the filling material, preferably 75 % by dry weight to 95 % by dry weight of the filling material, more preferred 85 % by dry weight to 95 % by dry weight of the filling material.

[0019] A filling material in an oral pouched product as disclosed herein and having a relatively low pre-use moisture content may be perceived by users to be fresh and agreeable to handle when taking it out of a user container and applying it in the mouth.

[0020] It may be preferred that the moisture content of the filling material in the oral pouched products as disclosed herein is 20 % by weight or less, or even 15 % by weight or less.

[0021] It may be preferred that the water insoluble substrate particles and preferably also the filling material comprising the water insoluble substrate particles contain or contains a low amount of fines.

[0022] The water insoluble substrate particles may contain less than 0.5 % by weight of particles passing through a sieve having a mesh size of 250 μm.

[0023] It may further be preferred that the filling material contains less than 0.5 % by weight of particles passing through a sieve having a mesh size of 250 μm.

[0024] A mesh size of 250 μm corresponds to a particle size in the order of a small to medium-sized grain of sand. Such particles are extremely unpleasant if they escape out through the cover material into the oral cavity of a user as they give rise to a gritty and dry mouthfeel which may linger for a long time after the product has been placed in the oral cavity, especially if the particles are non-soluble particles.

[0025] The water insoluble substrate particles are preferably of substantially the same size, having a narrow particle size distribution. A particulate material being constituted by ball-shaped particles with a generally spherical shape and having a narrow particle size distribution, has a predictable packing pattern and bulk volume with a void volume in the particulate material that remains substantially constant even if the particles shift position inside the liquid permeable pouch, e.g., as a result of mechanical working of the pouch by a user, when tucking the pouch in place in the mouth.

[0026] The filling material as disclosed herein may contain a sugar alcohol, such as maltitol, mannitol or isomalt, or combinations of two or more different sugar alcohols.

[0027] The filling material as disclosed herein preferably contains at most 15 % by dry weight of the filling material of sugar alcohol, preferably at most 10 % by dry weight of the filling material of a sugar alcohol and most preferred less than 5 % by dry weight of the filling material of a sugar alcohol. The filling material may be free of sugar alcohol.

[0028] It may be particularly preferred that substantially all nicotine in the filling material is located on an outer surface of the water insoluble substrate particles. In an oral pouched product as disclosed herein, it may be preferred that at least 85 % of the nicotine, such as at least 90 % of the nicotine, is located on the outer surfaces of the water insoluble substrate particles.

[0029] By having the nicotine concentrated on the surfaces of the water insoluble substrate particles, the nicotine is in-homogeneously distributed in the filling material and is readily available for dissolution in saliva which flows into the interstices between the water insoluble substrate particles. This is in contrast to substrate particles having the nicotine absorbed into the structure of the substrate particles or being mixed into substrate material which is formed into particles by processes such as extrusion.

[0030] The one or more water soluble components and other additives are preferably applied to the water insoluble substrate particles of the water insoluble particulate material in the filling material after the water insoluble substrate particles have been formed. The one or more water soluble components and other additives may be added as a liquid/aqueous mixture to the water insoluble substrate particles. All added components may be comprised in the same mixture. Alternatively, different components may be added in different application steps, e.g., a flavorant may be added in a separate step from an active agent such as the nicotine. By applying the one or more water soluble components and other additives to pre-formed water insoluble substrate particles, a major part of the additives will remain on or at the surface of the water insoluble substrate particles and will not penetrate into the interior of the water insoluble substrate particles, such that all or substantially all additives are present on or at the surface of the water insoluble substrate particles in the filling material. The water insoluble substrate particles are preferably homogeneous hydrophilic particles,

such as particles of one or more of microcrystalline cellulose, water insoluble starch and silica. It may further be preferred that the water insoluble substrate particles are constituted by mono-component particles of one or more of microcrystalline cellulose, water insoluble starch and silica. Microcrystalline cellulose may be particularly preferred due to being readily available in food-grade varieties.

[0031] The pouched product as disclosed herein may have a filling degree of the liquid permeable pouch which is 80 % or less, preferably 75 % or less, as measured according to the method disclosed herein. By leaving room for moving the water insoluble substrate particles in the liquid permeable pouch, nicotine release may be promoted by moving the water insoluble substrate particles in the pouch and thereby exposing new particles to saliva. Furthermore, an oral pouched product having a relatively low filling degree, such as 80 % or less, is more malleable than a tightly filled pouch and conforms better to the space between a user's lip and gum. The generally spherical, ball-shaped water insoluble substrate particles contribute to the malleability of the oral pouched product as the particles may shift position almost frictionless in the pouch due to the contact areas between the particles being minimal. The oral pouched product may therefore be perceived by a user as being easier to tuck in place under the lip and being more comfortable to use than a less malleable oral pouched product.

[0032] The liquid permeable pouch may be formed from a nonwoven material, such as a nonwoven material comprising staple fibres of regenerated cellulose. Nonwoven materials such as bonded, carded webs of staple fibres of regenerated cellulose are highly suitable for use in the liquid permeable pouch as disclosed herein, as they are hydrophilic and allow saliva to pass in and out of the pouch as well as being absorbed and transported along the fibres in the material.

[0033] The nicotine may be added to the water insoluble substrate particles of the filling material in the form of a nicotine compound. The nicotine compound may be a nicotine base and/or may be selected from nicotine hydrochloride, nicotine dihydrochloride, nicotine monotartrate, nicotine bitartrate, nicotine bitartrate dihydrate, nicotine sulphate, nicotine zinc chloride monohydrate and nicotine salicylate, nicotine benzoate, nicotine polacrilex and any combination thereof.

[0034] The filling material of the oral pouched product as disclosed herein is a tobacco free filling material or a filling material having a low tobacco content, the filling material comprising tobacco material in an amount of at most 10 %, preferably from 0.05 % to 1 %, based on the total weight of the filling material. In such case, the tobacco material may be a nicotine source. The water insoluble substrate particles in the filling material as disclosed herein is preferably constituted by tobacco free particles, such as tobacco free particles of microcrystalline cellulose, water insoluble starch, silica, or a mixture of two or more different types of tobacco free particles. A filling material or water insoluble substrate particles containing only trace amounts of tobacco, below 0.05 % by total weight of the filling material, is considered to be tobacco free.

[0035] The filling material described herein may further comprise an additive selected from the group consisting of a pH adjusting agent, a flavouring agent, a sweetener, a humectant and any mixture thereof. The additive may be a flavouring agent, such as a synthetic flavour, a plant-based flavour, a flavour oil, a hydrophobic flavour oil such as an essential oil, such as a nature-identical flavour. As used herein, a nature-identical flavour is a synthetic flavour which is chemically identical to natural flavourings but is prepared or extracted using chemical methods. The flavouring agent may be a mixture of different flavours. The flavouring agent may be stable at pH > 7. Further, the flavouring agent of the filling material in the oral pouched nicotine product as described herein may be a hydrophobic flavouring agent such as a hydrophobic flavour oil.

[0036] Examples of flavours include bergamot, eucalyptus, orange, mandarin, citrus, lemon, peppermint, spearmint, mint, menthol, liquorice, wintergreen, whiskey, rum, cherry, various berries, tobacco, coffee, vanilla, lime, apple, peach, carvone, limonene and any combination of two or more thereof. In an example, the flavour comprises tobacco flavour.

[0037] The filling material of the oral pouched nicotine product as described herein may comprise within the range of from about 0.5 % to about 3.0 % by weight of a flavouring agent, based on the total weight of the filling material.

[0038] The humectant may be glycerol and/or propylene glycol. The sweetener may be an artificial sweetener.

DEFINITIONS

[0039] The terms *"oral"* and *"oral use"* refer to a use of a product in contact with mucous membranes in the oral cavity of a human being, such as buccal placement of the product in the oral cavity. The products for oral use as disclosed herein are intended to be placed in their entirety in the oral cavity and are not intended to be swallowed.

[0040] As used herein the terms *"pouched product for oral use"* or *"oral pouched product"* refer to a portion of a smokeless composition containing saliva extractables which are contained in a saliva-permeable pouch. The saliva-permeable pouch is commonly made from a flexible, saliva-permeable material such as a nonwoven material.

[0041] A *"particle"* as used herein is a three-dimensional piece of material having a maximum dimension of less than 5 mm and an aspect ratio of from 0.3 to 1. The *"aspect ratio"*, A_R, as used herein, is calculated as the width, w, of the particle divided by the length l, of the particle where the length is determined as the largest dimension of the particle and the width is determined as the largest dimension orthogonal to the length: $A_R = l / w$. A particle having an aspect ratio of 1 may e.g., be a perfect sphere or a cube. The particles which are useful as the particulate material in the filling

material of the oral pouched products disclosed herein have a generally spherical shape, referred to herein as a "ball-shape", with an aspect ratio of 0.8, or above. The particles may have generally smooth outer surfaces or may have microscopic aberrations in the outer surfaces.

[0042] As used herein, the expression *"narrow particle size distribution"* intends particles varying in diameter by ± 30 % or less, preferably as ± 20 % or less, most preferably as ± 10 % or less. The particle size distribution and shape of the particles may be determined by image analysis using Dynamic Image Analyzer such as a QicPic instrument 'from Sympatec GmbH.

[0043] The diameter of a water insoluble substrate particle as described herein may be calculated as the diameter of a circle of equal projection area, which is the diameter of a circle that has the same area as the projection area of the particle. In this context, the projection area is the area resulting from a two-dimensional projection of the three-dimensional particle. As set out herein, image analysis may be used for determining the diameter of the particles described herein. The image analysis may be performed using a Sympatec GmbH instrument, as described herein.

[0044] The terms *"d10", "d50"* and *"d90",* or *"d10 value", "d50 value"* and *"d90 value"* used herein refer to the value of the particle diameter in a cumulative distribution of a group of particles with respect to volume. For example, if d50 = 0.8 μm, then 50 % of the particles in the sample are larger than, i.e., have a diameter that is larger than, 0.8 μm, and 50 % of the particles in the sample are smaller than, i.e., have a diameter that is less than, 0.8 μm. Accordingly, d50 is the median particle size distribution In a further example, if d10 = 0.8 μm, then 10 % of the particles have a diameter that is less than 0.8 μm. If d90 = 0.8 μm 90 % of the particles have a diameter that is less than 0.8 μm. The two values, d10 and d90, define the range of particle sizes of a particle sample. The small number of particles having diameters outside the range defined by d10 and d90 may be disregarded. A sample having a narrow particle size distribution has a d90/d10 ratioof 1, or approximately 1.

[0045] The roundness of a particle is the ratio of the averaged radius of curvature of all convex regions to the circumscribed circle of the particle and is calculated according to the formula:

$$Roundness = \frac{\sum_{i=1}^{n}\left(\frac{r_i}{R}\right)}{n}$$

where:

R = Radius of the circumscribed circle
r_i = Radius of the inscribed circle at convex corner i.

[0046] The sphericity, which may be denominated "S", is a measurement of how close a particle is to be a mathematically perfect sphere. The sphericity S is the ratio of the perimeter of the equivalent circle, P_{EQPC}, to the real perimeter, P_{real}. The perimeter of the equivalent circle, $P_{EQPC,}$ is the perimeter of a circle that has the same area as the projection area of the particle. In this context, the projection area is the area resulting from a two-dimensional projection of the three-dimensional particle. A particle having a sphericity value S equal to 1 has the shape of a perfect sphere. The sphericity may be calculated based on a measurement using image analysis on a sample of particles, wherein the projected area A and the projected real perimeter P_{real} are and recorded. The image analysis may be performed using the instrument from Sympatec GmbH, as described herein. The sphericity may be calculated according to the equation:

$$S = \frac{P_{EQPC}}{P_{real}} = \frac{2\sqrt{\pi \cdot A}}{P_{real}}$$

[0047] The ball-shaped particles as disclosed herein may be particles having, in combination, an aspect ratio of 0.8 or above and a sphericity of 0.8 or above. The ball-shaped particles as disclosed herein may further be particles having a roundness of 0.4 or above in combination with an aspect ratio of 0.8 or above and a sphericity of 0.8 or above. As set out herein, these parameters may be measured by a Dynamic Image Analyzer from Sympatec GmbH, or equivalent equipment.

[0048] A *"water insoluble particle"* as referred to herein is a particle which does not dissolve when subjected to saliva

in the oral cavity of a user and which retains or substantially retains its shape when incorporated in a pouched product for oral use. The water insolubility also implies that the particle size of the water insoluble substrate particles as referred to herein does not diminish or at least does not diminish by more than 1 % during use of an oral pouched product incorporating the water insoluble substrate particles. The shape and the size of the water insoluble substrate particles may remain substantially unaffected during use. However, a certain amount of swelling of the water insoluble substrate particles may occur. The swelling should preferably be less than 30 % of the pre-use bulk volume of the water insoluble substrate particles and more preferably less than 20 % of the pre-use bulk volume of the water insoluble substrate particles.

[0049] As used herein, the term *"moisture content"* refers to the percent by weight, wt%, of oven volatile substances, such as water and other oven volatiles (e.g., propylene glycol) which is present in a component material, a composition or a product and is determined according to the Loss On Drying (LOD) method disclosed herein.

[0050] The *"dry weight"* of a material, a composition, or a product is calculated by detracting the amount of moisture from the total weight of the material, composition or product, the moisture content being determined by the Loss On Drying (LOD) method as disclosed herein.

[0051] The term *"additional component"* refers to any component except water, which is present in addition to the particles of the particulate material in the filling material as disclosed herein, such as salts (e.g. sodium chloride, potassium chloride, magnesium chloride, calcium chloride and any combinations thereof), pH adjusters (e.g. sodium hydroxide, potassium hydroxide, potassium carbonate, sodium carbonate or sodium bicarbonate), flavouring agents, sweeteners, colorants, humectants (e.g. propylene glycol or glycerol), antioxidants, preservatives (e.g. potassium sorbate), binders, tobacco and non-tobacco plant material. The water-soluble component or water-soluble components which are part of the filling material in the oral pouched products as disclosed herein constitute one or more additional components.

[0052] The terms *"flavour" or "flavouring agent"* are used herein for substances used to influence the aroma and/or taste of the oral pouched product. The flavours may be any food-grade natural or synthetic flavour as known in the art and may include without limitation, essential oils, single flavour compounds, compounded flavourings, and extracts.

[0053] By *"tobacco"* or *"tobacco material"* is meant any part, e.g., leaves, stems, stalks, and flowers, of any member of the genus Nicotiana.

[0054] By a *"cover material"* as used herein is implied any suitable saliva permeable packaging material as known in the art. The cover material may also be referred to as *"pouch material"* and may be a nonwoven material, a material made by conventional textile production methods such as weaving or knitting or may be an apertured plastic film or netting. A nonwoven material suitable for use as cover material may be a nonwoven material comprising staple fibres, such as staple fibres of regenerated cellulose e.g., viscose rayon staple fibres or lyocell fibres and a chemical binder, such as a polyacrylate binder. Such nonwoven materials are commonly produced by carding the staple fibres to form a fibrous web, followed by consolidating the carded fibrous web by means of the binder. Alternatively, the nonwoven material may comprise fibres which are formed into a nonwoven web by spunbonding, hydroentangling, meltblowing, etc. The fibres used in such processes are generally thermoplastic fibres which are thermally bonded to form a coherent nonwoven web. The covering material may optionally comprise additional components such as flavouring agents and/or colorants.

[0055] A common way of making a pouched product having a generally rectangular pillow-like shape, is either to provide the cover material as a seamless endless tube or to form a flat web of cover material into an endless tube which is provided with a continuous seal in the longitudinal direction of the endless tube. The endless tube is subsequently intermittently sealed in the transverse direction of the endless tube while filling the endless tube with filling material into pockets which are created between the transverse seals. Individual pouched products are severed from the filled and sealed tube of cover material and are usually packed in user containers. Sealing of the cover material may be made with any suitable method or combination of methods, such as by means of adhesive, heat sealing, ultrasonic welding, needling, etc. Heat sealing and ultrasonic welding require the cover material to contain at least a functional amount of thermoplastic material, such as thermoplastic fibres or thermoplastic binders.

[0056] Pouched products for oral use are normally sized and configured to fit comfortably and discreetly in a user's mouth between the upper or lower gum and the lip. The most common shape for pouched products for oral use is a pillow-shape which is generally referred to as a *"rectangular shape"*, based on the flat-out shape of the saliva-permeable pouch, before it is filled. Pouched products for oral use may have a maximum length within the range of from 25 mm to 40 mm as measured in the longitudinal direction of the product and a maximum width within the range of from 5 mm to 20 mm as measured in the transverse direction of the product. The maximum width of an oral pouched product is commonly the width of the product as measured along an end seal. The pre-use thickness of the pouched product is normally within the range of from 2 mm to 8 mm. The total weight of a pouched product for oral use is typically within the range from about 0.3 g to about 3.5 g, such as from about 0.5 g to 1.7 g, per pouched product. The volume of a portion of filling material in a pouch is commonly in the range of from 0.5 cm^3 to 1.5 cm^3, depending on the size of the pouch.

[0057] A *"user container"* is a consumer package having a shape and a size adapted for conveniently carrying the user container in a pocket or in a handbag. A user container commonly contains in the range of from 10 to 30 oral pouched products. The pouched products may be placed randomly in the user container or may be arranged in a pattern,

for instance as disclosed in WO 2012/069505 A1. The user container may include a disposal compartment for storage of used oral pouched products. The disposal compartment is separated from the compartment in the container where the fresh, non-used, oral pouched products are stored until use.

[0058] The amount of nicotine in the filling material may be from 0.6 % to 1.7 %, or 0.8 to 1.4 %, or 1.0 to 1.2 %, based on the total weight of the filling material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0059] The present invention will be further explained hereinafter by means of non-limiting examples and with reference to the appended drawings wherein:

Figure 1 shows a pouched product for oral use;
Figure 2 shows a portion of a filling material in the pouched product of Fig. 1;
Figure 3 shows test equipment for use when determining filling degree of an oral pouched product; and
Figure 4 shows a schematical view of an image analysis instrument.

DETAILED DESCRIPTION

[0060] The pouched product 1 for oral use which is shown in Fig. 1 comprises a liquid permeable cover material 2 and a portion sized amount of a filling material 3 comprising a plurality of water insoluble substrate particles 4 enclosed by the liquid permeable cover material 2. The cover material 2 may be any suitable type of cover material as disclosed herein and is formed into a generally rectangular pouch into which the filling material 3 has been inserted.

[0061] A common way of making a pouched product having a generally rectangular pillow-like shape, such as the pouched product 1 shown in Fig. 1, is either to provide the cover material as a seamless and endless tube or to form a flat web of cover material into an endless tube which is provided with a continuous seal in the longitudinal direction of the endless tube. The endless tube is subsequently intermittently sealed in the transverse direction of the endless tube while filling the endless tube with filling material into pockets which are created between the transverse seals. Individual pouched products are severed from the filled and sealed tube of cover material and are usually packed in user containers. Sealing of the cover material may be made with any suitable method or combination of methods, such as by means of adhesive, heat sealing, ultrasonic welding, needling, etc. Heat sealing and ultrasonic welding require the cover material to contain at least a functional amount of thermoplastic material, such as thermoplastic fibres or thermoplastic binders.

[0062] The longitudinal seal created during manufacturing appears as a longitudinal seal 6 extending along the length l of the pouched product 1 shown in Fig. 1. No such seal will be present if the cover material is provided in the form of an endless seam-less tube. The transverse seals form end seals 7 which define the width w of the pouched product 1. The pouched product 1 has a first main surface 8 and a second main surface 9 and a thickness t being defined as the greatest perpendicular distance between the first main surface 8 and the second main surface 9.

[0063] The particles 4 of the water insoluble particulate material may constitute a very high proportion of the total dry weight of the filling material 3, such as 65 % by dry weight to 99 % by dry weight of the filling material, as set out herein.

[0064] The filling material 3 further comprises one or more water soluble components 11, such as flavours, sweeteners, active ingredients such as nicotine, etc. as disclosed herein.

[0065] A part of a filling material 3 for an oral pouched product as disclosed herein is shown in Fig. 2, the filling material 3 comprising a plurality of generally spherical, ball-shaped, water insoluble substrate particles 4 having a thin layer of water soluble components on the surfaces of the particles 4.

[0066] As set out herein, the particles 4 of the filling material have a relatively large average particle size within the range of from 0.25 mm to 2.0 mm.

[0067] Fig. 2 shows only a very small number of particles 4. In a full portion of filling material 3 for an oral pouched product 1, the number of particles 4 in the water insoluble particulate material is considerably higher, such as in the order of 150 particles or more which means that a large majority of the particle surfaces will be located in the interior of the filling material 3.

TEST METHODS

Method for determining moisture content, Loss On Drying, LOD

[0068] The moisture content as referred to herein may be determined by using a method based on literature references Federal Register/ vol.74, no. 4/712-719/Wednesday, January 7, 2009/Notices " Total moisture determination" and AOAC (Association of Official Analytical Chemics), Official Methods of Analysis 966.02: "Moisture in Tobacco" (1990), Fifth Edition, K. Helrich (ed). In this method, the moisture content is determined gravimetrically by taking 2.5±0.25 g sample

and weighing the sample at ambient conditions, herein defined as being at a temperature of 22 °C and a relative humidity of 60 %, before evaporation of moisture and after completion of dehydration. Mettler Toledo's Moisture Analyzer HB43, a balance with halogen heating technology, is used (instead of an oven and a balance as in the mentioned literature references) in the experiments described herein. The sample is heated to 105 °C (instead of 99.5±0.5 °C as in the mentioned literature references). The measurement is stopped when the weight change is less than 1 mg during a 90 second time frame. The moisture content as weight percent of the sample is then calculated automatically by the Moisture Analyzer HB43.

Method for determining particle size and particle shape by image analysis

[0069] Particle roundness, particle sphericity, aspect ratio, and particle size were determined using a QicPic image analysis instrument from 2012, Sympatec GmbH, ID No. 290-D, with Rodos/L dispersion line ID NO 214D and Vibri/L sample feeding ID NO 273, or equivalent equipment. A well dispersed particle flow is led through the image plane of the instrument, as shown in Fig. 4 where 21 is a pulsed light source, 22 is a beam expansion unit adaptable to measuring range, 23 is a dispersing unit, 24 is a particle flow, 25 is a lens and 26 is a camera. If the particles are small, a high number of particles per image frame may be captured, such as in the order of 50,000 to 100,000 particles per image frame. For larger particles, such as particles having a particle size from 300 μm to 3000 μm, the number of particles per image frame may be substantially less and may be in the order of from 300 to 2000 particles per image frame.

Sieving method

[0070] A commercially available particle screening equipment such as a *Retsch* / *AS 200 control* vibrating sieve may be used. A 10 g sample of the tested filling material or water insoluble substrate particles is placed on the sieve such as a sieve having a mesh size of 250 μm and is vibrated for 1 minute with an amplitude of 1 mm.

[0071] The weight of the upper fraction and the lower fraction is measured for the sample and the weights are used for calculating the proportion of the sample which has passed through the mesh.

Method for determining filling degree in an oral pouched product

[0072] The measurements are carried out at ambient conditions, as defined herein. The pouches 1 are applied in a frame 20 shown in Fig. 3 with a first transverse end seal 7' placed below a second transverse end seal 7". The pouches 1 are attached to the frame 20 by means of a double-sided tape applied to the first transverse end seal 7'. The frame 20 is designed to support the filled pouch 1 without compressing it. Following application of the filled pouch in the frame, the shortest distance between the upper surface of the filling material 3 and the first transverse seal 7', i.e., the height of the filling material 3 in the pouch 1, is determined using a digital tabletop caliper device having a resolution of 0.01 mm. A background LED light may be directed at the pouch 1 for improving content discernability. Care should be taken not to agitate or shake the filled pouch 1 during application of the pouch in the frame.

[0073] The filling degree of the oral pouched product is calculated by dividing the measured height of the filling material in the pouch with the inner distance between the first and second transverse end seals 7', 7" and is reported in percent (%) of the available filling height.

EXAMPLE

Sample preparation

[0074] Five different MCC materials were tested:

Table 1

Example 1	Vivapur MCC spheres 700 supplied by JRS Pharma, Germany
Example 2	Cellets 350 supplied by Pharmatrans, Switzerland
Reference 1	Avicel PH-200 supplied by JRS Pharma, Germany
Reference 2	Cellets 100 supplied by Pharmatrans, Switzerland
Reference 3	Crushed particles of Example 1. The particles were crushed by means of milling in a mortar during 3 minutes until the particles had formed a fine powder.

[0075] The tested materials according to Examples 1 and 2 and References 1 and 2 had a sphericity, aspect ratio and particle size as set out in Table 2 when measured at d50 with the image analysis instrument from Sympatec GmbH:

	Example 1	Example 2	Reference 1	Reference 2
Sphericity	0.817	0.804	0.810	0.842
Aspect ratio	0.962	0.913	0.742	0.875
Particle size (μm)	890	445	205	163

[0076] For each sample, a solution was prepared from 48.3 grams of 20 % nicotine in glycerine (supplied by CNT, Germany), 6.5 grams of potassium carbonate, 15 grams of sodium chloride, 1 gram of acesulfame K and 110.3 grams of water.

[0077] The nicotine-containing solution was then mixed with 809 g grams of the MCC material to be tested and 10 grams of peppermint flavor. The mixture was allowed to rest for 16 hours at room temperature without stirring resulting in nicotine containing particles.

[0078] The particles of the 5 different sample materials were then packed in rectangular pouches as shown in Fig. 1 and having a width, w, of 12.5 mm and a length, l, of 37 mm. The inner length of the pouch between the end seals 7 was 32 mm. Each pouch was filled with nicotine containing particles to a filling degree of approximately 65.6 %.

[0079] The pouch material which was used for all samples was a standard viscose nonwoven No. Z8732 from TENOWO GmbH.

Test procedure

[0080] Seven test persons were each given 5 containers with two sample products containing one of the tested filling materials in each container, in total 10 sample products per test person. The test persons were also given 10 glass vials for storing the samples after use.

[0081] Each vial was labelled with the sample to be put in the vial, e.g., "Example 1, 10 minutes", "Reference 3, 30 minutes", etc.

[0082] The test persons were instructed not to use any tobacco product or other nicotine containing product for at least 30 minutes before each test and to rinse the mouth with water before the test. The test persons were instructed to use the sample products in the way they normally would, but not to ingest any food or drink during the test period.

[0083] The tests were performed by the test persons by:

1. Selecting a vial at random and checking the label to see which sample to put in the vial.
2. Taking out a sample from the container containing the samples according to the label on the vial.
3. Placing the sample under the lip and letting it remain there for 10 or 30 minutes depending on what is written on the label on the vial in which the sample is to be put after use.
4. After use of the sample product, carefully removing the sample product with a pair of tweezers, while avoiding squeezing the sample.
5. Placing the used sample product in the assigned glass vial.
6. Storing the glass vials in a freezer until all sample products had been used.

[0084] The used samples were then analyzed for nicotine content. Non-used samples were also analyzed to establish original nicotine content. It was found that the filling materials of Example 1 and Example 2 had a nicotine release profile such that more than 30 % of the nicotine had been extracted after 10 minutes and more than 40 % of the nicotine had been extracted after 30 minutes. The filling material of Example 2, with water insoluble ball-shaped MCC particles having a particle size (d50) of 445 μm were found to have surprisingly good nicotine release properties, with approximately 40 % of the nicotine having been released already after 10 minutes and more than 55 % of the nicotine having been released after 30 minutes. The filling material with water insoluble ball-shaped MCC particles having a particle size (d50) of 890 μm was also found to have good nicotine release properties with slightly more than 30 % of the nicotine having been released after 10 minutes and more than 45 % of the nicotine having been released after 30 minutes.

[0085] The reference samples all showed a considerably lower nicotine release after 10 minutes, with only Reference 2 reaching an acceptable level of nicotine release after 30 minutes.

[0086] The results are shown in Table 3, below.

Table 3

Sample	0 min (mg)	10 min (mg)	30 min (mg)	10 min %	30 min %	Sample Weight* (g)
Ex.1	5.47	3.80	2.97	30.6	45.7	0.70
Ex 2	5.20	3.11	2.32	40.2	55.5	0.72
Ref. 1	2.60	2.02	1.78	22.4	31.7	0.35
Ref. 2	5.36	4.07	2.83	24.0	47.1	0.70
Ref. 3	4.39	3.64	3.03	17.0	31.0	0.60
*Including pouch material						

Claims

1. A pouched product for oral use comprising a liquid permeable pouch and a nicotine containing filling material enclosed by the pouch, wherein the filling material

    - is a tobacco free filling material or comprises tobacco material in an amount of at most 10 % by total weight of the filling material;
    - has a pre-use moisture content of from 1 % to 35 % by total weight of the filling material;
    - contains nicotine in an amount of from 0.5 % to 2 % by total weight of the filling material; and
    - comprises water insoluble substrate particles and one or more water-soluble components;

    wherein the water insoluble substrate particles are ball-shaped particles constituting at least 65 % by dry weight of the filling material, the water insoluble substrate particles having a particle size of from 0.25 mm to 2.0 mm.

2. A pouched product according to claim 1, wherein the water insoluble substrate particles have a particle size of from 0.25 mm to 1.5 mm.

3. A pouched product according to claim 2, wherein the water insoluble substrate particles have a particle size of from 0.25 mm to 1.0 mm.

4. A pouched product according to claim 3, wherein the water insoluble substrate particles have a particle size of from 0.25 mm to 0.6 mm, preferably from 0.25 mm to 0.5 mm.

5. A pouched product according to claim 1, wherein the water insoluble substrate particles have a particle size of from 0.3 mm to 2.0 mm.

6. A pouched product according to claim 5, wherein the water insoluble substrate particles have a particle size of from 0.3 mm to 1.5 mm.

7. A pouched product according to claim 6, wherein the water insoluble substrate particles have a particle size of from 0.3 mm to 1.0 mm.

8. A pouched product according to claim 7, wherein the water insoluble substrate particles have a particle size of from 0.3 mm to 0.6 mm, preferably from 0.3 mm to 0.5 mm.

9. A pouched product according to any one of the preceding claims, wherein the water insoluble substrate particles have an aspect ratio of 0.8 or above and a sphericity of 0.8 or above.

10. A pouched product according to any one of the preceding claims, wherein the water insoluble substrate particles comprise or consist of particles of microcrystalline cellulose, water insoluble starch, silica, or a mixture thereof.

11. A pouched product according to claim 10, wherein the water insoluble substrate particles comprise or consist of particles of microcrystalline cellulose.

12. A pouched product according to any one of the preceding claims, wherein the water insoluble substrate particles constitute 75 % by dry weight to 95 % by dry weight of the filling material, preferably 85 % by dry weight to 95 % by dry weight of the filling material.

13. A pouched product according to any one of the preceding claims, wherein the water insoluble substrate particles contain less than 0.5% by weight of particles passing through a sieve having a mesh size of 250 μm.

14. A pouched product according to any one of the preceding claims, wherein the filling material contains less than 0.5 % by weight of particles passing through a sieve having a mesh size of 250 μm.

15. A pouched product according to any one of the preceding claims, wherein the water insoluble substrate particles have a narrow particle size distribution.

16. A pouched product according to any one of the preceding claims, wherein the filling material contains at most 15 % by dry weight of the filling material of sugar alcohol, preferably at most 10 % by dry weight of the filling material of sugar alcohol and most preferred less than 5 % by dry weight of the filling material of sugar alcohol.

17. A pouched product according to any one of the preceding claims, wherein substantially all nicotine in the filling material is located on an outer surface of the water insoluble substrate particles.

18. A pouched product according to any one of the preceding claims, wherein a filling degree of the liquid permeable pouch is 80 % or less.

19. A pouched product according to any one of the preceding claims, wherein the liquid permeable pouch is formed from a nonwoven material, such as a nonwoven material comprising staple fibres of regenerated cellulose.

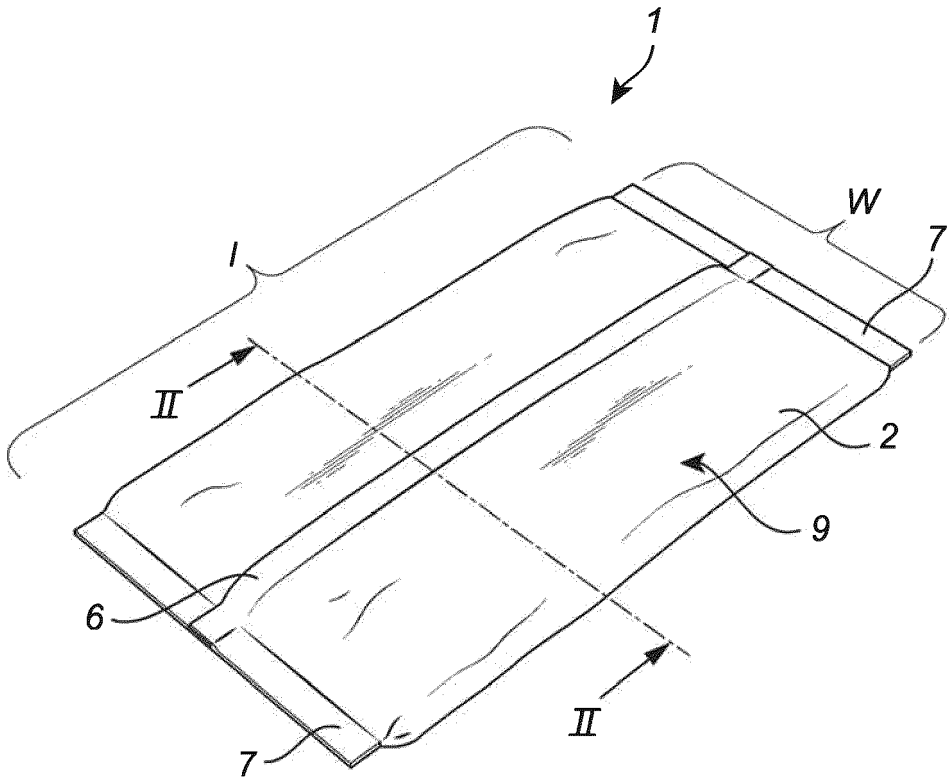

Fig. 1

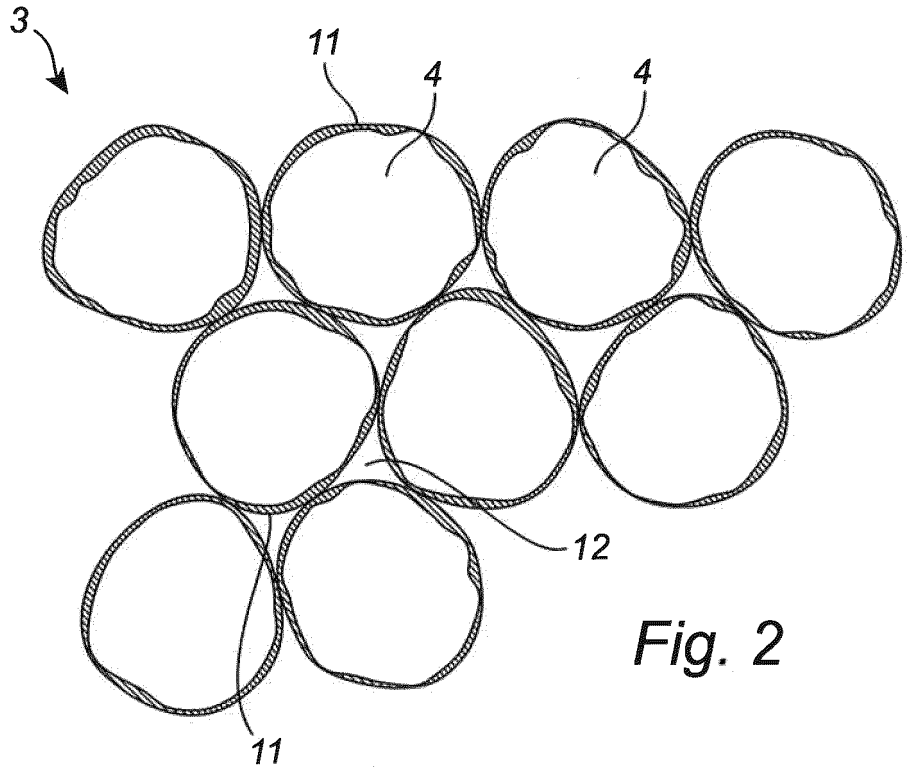

Fig. 2

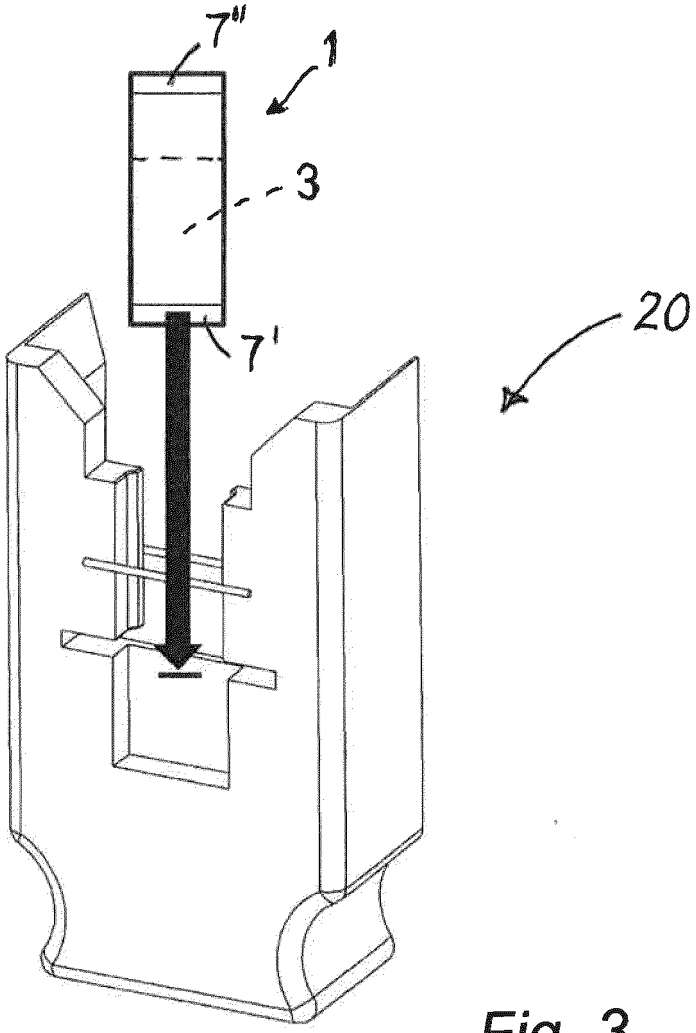

Fig. 3

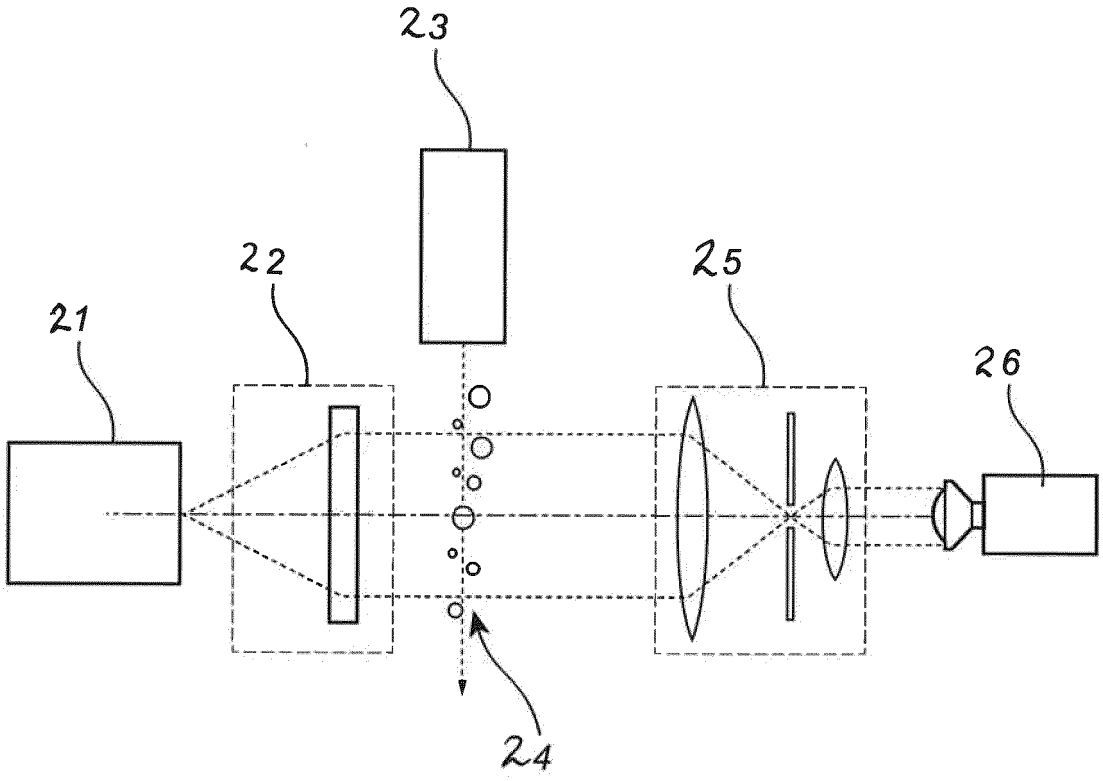

Fig. 4

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EUROPEAN SEARCH REPORT

Application Number
EP 22 17 1746

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 2021/004928 A1 (SWEDISH MATCH NORTH EUROPE AB [SE]) 14 January 2021 (2021-01-14) * page 1, line 5 - line 10 * * page 3, line 15 - line 21 * * page 3, line 25 - page 4, line 28 * * page 10, line 22 - page 11, line 20 * * page 13, line 17 - page 14, line 15 * * page 15, line 27 - line 33 * * page 17, line 15 - line 29 * * page 21, line 31 - line 32 * * page 22, line 10 - line 13 * * page 22, line 31 - page 23 * * page 25, line 1 - line 2 * * page 27, line 9 - page 29; claims 1-36 * -----	1-19	INV. A24B13/00 A24B15/16
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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	11 October 2022	Kirchhoff, Eva

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