

(19)



(11)

EP 4 293 148 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
20.12.2023 Bulletin 2023/51

(51) International Patent Classification (IPC):
D04H 3/013^(2012.01) G01N 33/543^(2006.01)

(21) Application number: **22179266.6**

(52) Cooperative Patent Classification (CPC):
D04H 3/013; G01N 33/54388

(22) Date of filing: **15.06.2022**

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
 Designated Extension States:
BA ME
 Designated Validation States:
KH MA MD TN

(71) Applicant: **LENZING AKTIENGESELLSCHAFT**
4860 Lenzing (AT)

(72) Inventor: **Köll, Berndt**
4810 Gmunden (AT)

(74) Representative: **Global Patent Management**
Lenzing AG
Werkstraße 2
4860 Lenzing (AT)

(54) **NONWOVEN LAYER COMPRISING A NETWORK OF SUBSTANTIALLY CONTINUOUS REGENERATED CELLULOSIC FIBERS**

(57) Nonwoven layer comprising a network of substantially continuous regenerated cellulosic fibers. The nonwoven layer has a wicking time of between 5 and 50 s/40mm, preferably between 8 and 20 s/40mm. The wick-

ing time can be determined by measuring the time it takes for the water to reach a level of 40 mm above water surface in a test arrangement according to Harmonized Non-wovens Standard Procedure NWSP 010.1.R0 (15).

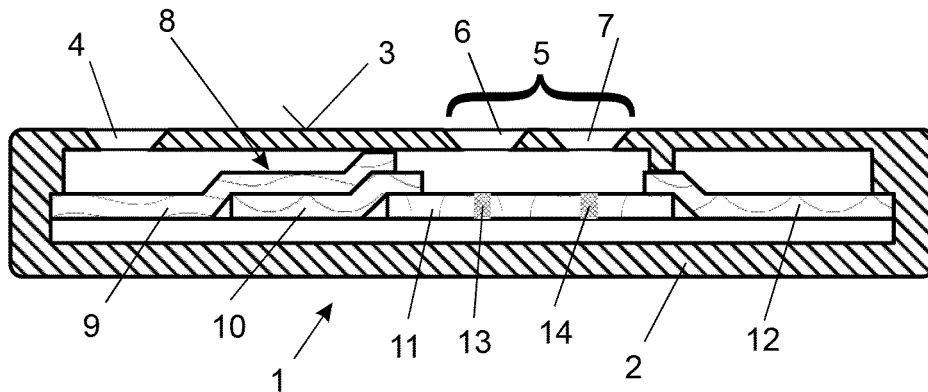


Fig. 1

EP 4 293 148 A1

Description**Field of the invention**

5 **[0001]** The present disclosure relates to the field of cellulosic nonwoven materials and especially to nonwoven materials having specific wicking properties. Such nonwoven materials can, for example, be used as fluid transporting layers in lateral flow assay kits.

Description of the Related Art

10 **[0002]** The current disclosure relates to improvements concerning the production and use of nonwoven layers comprising a network (also called "web") of substantially continuous regenerated cellulosic fibers. More specifically, the current disclosure relates to novel nonwoven layers that are produced according to the so-called solution-blown process and have improved wicking properties.

15 **[0003]** Cellulosic fibers can be produced by various processes. In one embodiment a lyocell fiber is spun from a lyocell spinning solution comprising cellulose dissolved in N-methyl morpholine N-oxide (NMMO) by a meltblown process, in principle known from e.g. EP 1093536 B1, EP 2013390 B1 and EP 2212456 B1. In jurisdictions where this is possible, the documents EP 1093536 B1, EP 2013390 B1 and EP 2212456 B1 are included herein by reference.

20 **[0004]** Where the term meltblown is used, it will be understood that it refers to a process that is similar or analogous to the process used for the production of synthetic thermoplastic fibers (filaments are extruded under pressure through nozzles and stretched to required degree by high velocity/high temperature extension air flowing substantially parallel to the filament direction), even though the cellulose is dissolved in solution (i.e. not a molten thermoplastic) and the spinning & air temperatures are only moderately elevated. Therefore the term "solution blown" may be even more appropriate here instead of the term "meltblown" which has already become somewhat common for these kinds of technologies. For the purposes of the present disclosure the term "meltblown" is used as a generic term, independent of the fiber material and the term "solution blown" is used for the production of cellulosic nonwovens from lyocell spinning solution.

25 **[0005]** It is also known to use other dissolvents than NMMO, such as ionic liquids or the like, to prepare the spinning solution. Spinning solutions that are prepared using such alternative solvents also fall under the scope of the term "lyocell spinning solution", as it is used herein.

30 **[0006]** In one embodiment for making a nonwoven web the fibers are contacted with a nonsolvent such as water (or water/NMMO mixture) by spraying, after extrusion but before web formation. The fibers are subsequently taken up on a moving foraminous support to form a nonwoven web, washed and dried.

35 **[0007]** Freshly-extruded lyocell solution ('solvent spun'), which will contain only, for example, 5-15% cellulose, behaves in a similar way to 'sticky' and deformable thermoplastic filaments. Causing the freshly-spun filaments to contact each other while still swollen with solvent and with a 'sticky' surface under even low pressure will cause merged filament bonding, where molecules from one filament mix irreversibly with molecules from a different filament. Once the solvent is removed and coagulation of filaments completed, this type of bonding is impossible.

40 **[0008]** Processes for the production of a nonwoven layer comprising a network of substantially continuous regenerated cellulosic fibers are documented and published in detail in WO 2007/124521 A1, WO 2018/071928 A1, WO 2018/184941 A1 and WO 2020/016296 A1 and the literature cited therein. In jurisdictions where this is possible, the documents WO 2007/124521 A1, WO 2018/071928 A1, WO 2018/184941 A1 and WO 2020/016296 A1 are included herein by reference.

45 **[0009]** Lateral flow assays (LFA) have been introduced early and were further developed over the last decades. The technology is widely used as a diagnosis-supporting tool in healthcare, food industry, chemical laboratories and others. LFAs are clinically well established, reliable and cost effective test devices. They make use of a disposable test strip and can evaluate biological markers in bodily fluids like saliva and urine. The global market for LFA is estimated at approx. 6 bio USD at a compound average growth rate (CAGR) of approx. 8%. The global COVID-19 pandemic further stimulated the wide use of reliable, sensitive and specific LFA's.

50 **[0010]** An LFA is a portable strip in a plastic housing that consists of several parts. The sample pad is the first area to get in contact with the sample fluid. Its major purpose is to allow the liquid to flow through the test kit reasonably fast and in a continuous way. Through its wicking performance it guides the sample to the so called test membrane via a conjugate pad. The membrane is the most critical element in any LFA strip. It contains the test result line as well as the control line. Nitrocellulose is most commonly selected as membrane carrier material. An absorbent pad absorbs excess sample fluid.

55 **[0011]** In general, for sample pads and absorbent pads cellulose containing products like laboratory papers are being used. The papers are selected for they increased and constant wicking speed as well as for trouble free processing like in slitting processes for cutting the narrow strips. To improve the wicking properties it is known to use special nonwoven layers comprising glass fibers and/or synthetic fibers.

Summary

[0012] The present disclosure provides novel cellulosic nonwoven layers having advantageous wicking rates and can be used, inter alia, as a sample fluid transporting layer in a lateral flow assay. Further the present disclosure provides lateral flow assays comprising the nonwoven layer. Still further the present disclosure provides methods for use of the nonwoven layer an/or the lateral flow assay.

[0013] According to one aspect, the present document discloses a nonwoven layer comprising a network of substantially continuous regenerated cellulosic fibers which has a wicking time of between 5 and 50 s/40mm, preferably between 8 and 20 s/40mm, wherein the wicking time is determined by measuring the time it takes for the water to reach a level of 40 mm above liquid surface in a test arrangement according to Harmonized Nonwovens Standard Procedure NWSP 010.1.R0 (15).

[0014] Nonwoven materials that have a fast wicking time are advantageous for a plurality of uses, for example a fluid transporting layer in lateral flow assay test kits. It has been surprisingly found that nonwoven layers according to the present disclosure exhibit wicking times that exceed the wicking times of laboratory papers which are currently used in the field of lateral flow assays. The performance of the nonwoven materials described herein even compares with special high-tech wicking materials comprising microfiber glass and/or polyester fibers. Still, the nonwoven material according to the present disclosure can be made of 100 percent cellulosic material and therefore is ecological and biodegradable.

[0015] The term "substantially continuous regenerated cellulosic fibers", as it is used herein, refers to fibers that are produced in a continuous spinning process, wherein the fibers are not cut into staple fibers. Preferably the production of the substantially continuous regenerated cellulosic fibers comprises a solution blown process.

[0016] The measurement of the wicking time can preferably be performed according to the test arrangement described in Harmonized Nonwovens Standard Procedure NWSP 010.1.R0 (15), wherein the time it takes for the water to reach a level of 40 mm above water surface is accurately measured as the wicking time. It should be noted that similar internal or official standards can be used for the measurement of the wicking time and/or the wicking rate, as long as they do not significantly alter the measurement results and allow for an assured determination whether or not the measured property falls into the claimed range.

[0017] In one embodiment, the nonwoven layer according to the present disclosure can have a basis weight of between 15 g/m² and 200 g/m², preferably between 20 g/m² and 100 g/m². It has been surprisingly found that the nonwoven layers according to the present disclosure can be used at a lower basis weight compared to currently used wicking materials and still produce the required performance. This, inter alia, reduces material costs and reduces the environmental load. The basis weight (also designated as "mass per unit area") can preferably be determined according to Nonwoven Standard Procedure NWSP 130.1.R0 (15).

[0018] According to another embodiment, the nonwoven layer can have a porosity of between 50 % and 90 %, preferably between 80 and 90%. This allows for a high liquid uptake and good wicking speed at a low basis weight.

[0019] The porosity of a material is defined as the fraction of the volume of voids over the total volume of the material and can preferably be measured by mercury porosimetry according to ISO 15901-1:2016.

[0020] Preferably, the nonwoven layer according to the present disclosure can have a specific pore volume of between about 2 cm³/g and about 5 cm³/g, preferably between about 3 cm³/g and about 4 cm³/g.

[0021] The specific pore volume is defined according to the following formula:

$$\text{specific pore volume} = (\text{porosity}) / (\text{raw density} * 100)$$

[0022] The specific pore volume can preferably be determined according to ISO 15901-1:2016.

[0023] In another embodiment, the nonwoven layer can have a median pore size of between 50 and 120 μm, preferably between 80 and 100 μm. The pore size and pore size distribution can be adjusted to the specific wicking fluid, the nonwoven layer is produced for. The pore size distribution can preferably be measured via Hg-Pososimetry according to ISO 15901-1:2016. A size distribution with a median pore size in the range specified above can be preferred for essentially aqueous substances.

[0024] The pore size, specific pore volume and/or porosity of the nonwoven layer can be adjusted by several production parameters, especially the stretching air pressure, the amount of coagulation liquid, the extrusion speed (which can be indicated as the mass of spinning solution extruded through each spinning hole in a given time, e.g. g/min), the amount and density of holes and the hole diameters of the spinneret, the distance between the spinneret and the support, where the nonwoven layer is formed. Generally, a higher amount of coagulation within the air gap between the Spinneret and the support will produce a higher pore size.

[0025] According to another embodiment, the fibers in the nonwoven layer can be finish free. "Finish free", as the term is used herein, denotes fibers that have not been subjected to a finishing step and therefore are free of finishing agents. The nonwoven layer can also be produced with production methods that ensure that the layer is essentially free of

substances that could affect any test results in a lateral flow assay.

5 **[0026]** In another preferred embodiment, the nonwoven layer can be essentially free of copper and/or nickel. This can be realized by the use of operating fluids (in particular lyocell spinning solution, coagulation fluid, washing liquor, gas flow, etc.) during the manufacturing process that are substantially free of heavy metal sources such as copper salt. As a result of this design of the manufacturing process, the cellulosic fibers according to the present disclosure may be of high quality and may substantially consist of pure microfibrillar cellulose. The absence of any mentionable heavy metal impurities in the manufacturing process prevents highly undesired decomposition of involved media (in particular of the lyocell spinning solution) and therefore allows to obtain highly reproducible and highly pure cellulose fibers that are biodegradable.

10 **[0027]** The term "essentially free of copper and/or nickel", as it is used herein, denotes that these substances are maximally present in practically negligible amounts. For example, a copper contents of less than 5 ppm and/or a nickel contents of less than 3 ppm is practically negligible in most cases and therefore can be considered as essentially free of copper and/or nickel, respectively.

15 **[0028]** According to still another embodiment, at least a part of the nonwoven layer can be directly manufactured from lyocell spinning solution in a solution blown process. Such a nonwoven layer forms a network of substantially endless regenerated cellulosic fibers. The nonwoven layer can easily, yet reliably be produced and can be provided with a very homogeneous pore size distribution. The cellulosic fibers can further improve the liquid wicking and liquid absorbency properties. Furthermore, the nonwoven layer may contain essentially only cellulose, thus, showing good biodegradability. The cellulosic nonwoven layer, directly manufactured from lyocell spinning solution, can be manufactured according to a variant of a solution blown process (also called spunlaid nonwoven process), e.g. as described in WO 2018/184038 and WO 2018/184932. In jurisdictions where this is possible, the documents WO 2018/184038 and WO 2018/184932 are included herein by reference. In this process, a (lyocell) cellulose spinning mass is extruded simultaneously through a spinneret containing closely-spaced meltblown jet nozzles. The extruded spinning solution is then attenuated using high velocity air streams and the nonwoven web/layer is formed on a moving surface. Finally the nonwoven web is washed and dried. By carefully adjusting the spinning parameters (cellulose concentration of the spinning mass, spinneret extrusion rate, attenuating air stream velocity, etc.), the strength- and liquid-transport-properties of the formed nonwoven can be tailored to the needs. Such a nonwoven layer formed by the above mentioned process may thus provide good absorbency, fast wicking, fast liquid uptake, good spread-ability of liquid, enhanced dimensional stability (wet and dry), biodegradability and sustainability; all without the need of adding binders or chemicals.

20 **[0029]** The nonwoven layer can also be combined with composite materials, such as pulp, preferably derived from wood, staple fibers, binders, wicking controlling agents or the like. Wicking controlling agents are substances that are applied to influence the wicking speed of the nonwoven material. For example by changing the hydrophilic properties of the fibers, the wicking properties of the nonwoven material can be changed to a certain extent. Pulp can, for example, be applied to the solution blown nonwoven material after the formation of the nonwoven layer via processes such as wetlaid or airlaid. Such processes are per se known in the art. The composite material can subsequently be treated by a hydroentanglement-step to improve the bonding of the pulp and the nonwoven layer.

25 **[0030]** In another preferred embodiment, the cellulosic fibers in the nonwoven layer can be multibonded by merging, hydrogen bonding and/or physically intermingling. Thus, the dimensional stability of the nonwoven layer may be improved, which also improves the machinability of the nonwoven layer.

30 **[0031]** According to another aspect of the present disclosure, the fibers of the nonwoven layer can have diameters ranging from 1 μm to 250 μm , preferably from 2 μm to 75 μm . This scope includes cellulosic materials that are made according to a meltblown process. In this case the larger diameters in particular belong to merging points. Most of the suitable meltblown materials according to the present disclosure may show fiber diameters of up to 75 μm only, however materials with the larger diameters may be suitable, as well.

35 **[0032]** According to a further aspect, the present document discloses the use of a nonwoven layer as disclosed herein for the production of a sample fluid transporting layer in a lateral flow assay. This allows for a cost efficient production fluid transporting layers with beneficial properties that are biodegradable. The novel nonwoven layer according to the present disclosure can be advantageously used for either a fluid transporting layer in an lateral flow assay, particularly as a material for the production of the sample pad and/or the absorbent pad, but also as a material for the production of the conjugation pad and/or even the test membrane.

40 **[0033]** According to another aspect the present document discloses a lateral flow assay comprising a housing with at least one sample port and at least one display port and at least one sample fluid transporting layer, wherein the at least one sample fluid transporting layer comprises at least one nonwoven layer according to an embodiment of the present disclosure. Such a lateral flow assay can be produced according to high-quality standards using up to 100% environmental-friendly or even biodegradable materials.

45 **[0034]** According to one embodiment, the lateral flow assay can have at least one fluid transporting layer, the fluid transporting layer comprising at least one of a sample pad, a conjugate pad, a test membrane and/or an absorbent pad, wherein at least one of the sample pad, the conjugate pad, the test membrane and/or the absorbent pad comprises at

least one nonwoven layer according to any of the embodiments disclosed herein.

[0035] Such a lateral flow assay can use the beneficial properties of the nonwoven layers disclosed herein. By using biodegradable or compostable materials also for the production of the housing of the lateral flow assay, environmental-friendly test assay kits can be provided that avoid the use of single-use plastic materials. The assays can therefore be fully biodegradable or even compostable. For example, the lateral flow assay can be made using a biodegradable or compostable material selected from a list comprising biopolymers such as cellulose, polylactic acid (PLA), cellulose acetate, polyhydroxyalkanoate (PHA) or the like.

Brief Description of the Drawings

[0036] Hereinafter, exemplary embodiments of the invention are described with reference to the drawings, wherein

Fig. 1 shows a sectional view of a lateral flow assay,

Fig. 2 shows a microscopic image of a nonwoven layer according to one embodiment,

Fig. 3 shows a microscopic image of a nonwoven layer according to another embodiment, and

Fig. 4 shows a diagram depicting the results of a porosimetry measurement of a nonwoven layer according to the present disclosure.

Detailed Description of the Drawings

[0037] Fig. 1 shows a lateral flow assay 1 having a plurality of sample fluid transportation layers 8 that are arranged in a housing 2. The housing 2 has, on an upper side 3 of it, several openings, namely at least one sample port 4 and at least one display port 5.

[0038] The display port 5 can have several separated sections, for example a result display port 6 and a test display port 7 as shown in Fig. 1. Depending on the test design and the specific properties of the test, different layouts of the housing 2 and the openings are possible, as is known by the skilled practitioner.

[0039] Inside the housing at least one sample fluid transporting layer 8 is arranged, which takes up a sample fluid at the at least one sample port 4 and transports the sample fluid by force of a wicking effect to the display port 5, where the sample fluid interacts with at least one marker material. Usually a first marker material interacts with a test result line 13, which visibly changes its color in case of a positive test result, and another marker material interacts with a control line 14 that visibly changes color when the sample fluid is present in an adequate amount.

[0040] The sample fluid transporting layer 8 usually has several parts that have a specific purpose. For example, the transporting layer 8 can comprise a sample pad 9, a conjugation pad 10, a test membrane 11 and an absorbent pad 12.

[0041] The sample pad 9 receives the sample fluid and acts as the first stage of the absorption process. The sample pad 9 can, in some cases, also contain a filter (not shown), to ensure the accurate and controlled flow of the sample.

[0042] The sample fluid moves along the sample pad 9 to reach the conjugate pad 10. The conjugate pad 10 comprises conjugated labels and antibodies (marker materials) that will bind to a target, if it is present in the sample fluid. The conjugate pad 10 also comprises control-antibodies that are specific for the sample fluid but not specific for the target. If the target is present, the immobilized conjugated antibodies and labels will bind to the target and continue to migrate along the transporting layer 8 with the sample fluid and move to the test membrane 11.

[0043] The test membrane 11 usually is a nitrocellulose membrane comprising lines with binding reagents that form at least one test result line 13 and one control line 14. As the sample moves along the test membrane 11, the binding reagents situated on the test membrane 11 will bind to the target at the test line and a colored line will form. Depending on the quantity of the target present, the density of the line will vary. Some assays can also provide for a quantification of the target concentration.

[0044] After the sample fluid has passed through the test membrane 11 it reaches the absorbent pad 12 which will absorb the excess sample fluid. The properties of the absorbent pad has an impact on the volume of sample fluid the test can incorporate.

[0045] For the performance of the lateral flow assay 1 the properties of the materials that are used for the sections of the fluid transporting layer 8 are very important. Especially for the two pads that are not directly involved in the biochemical processes, namely the sample pad 9 and the absorbent pad 12, but also for the conjugation pad 10 and the test membrane 11, a good wicking rate, a proper fluid absorption capacity and a low basis weight is desired. Further, the materials should be available at a reasonable price and must not interfere with the biochemical properties of the sample fluid.

[0046] Fig. 2 and 3 show microscopic images of nonwoven layers according to the present disclosure. The nonwoven layers have been produced in a solution blown process from lyocell solution as a network of substantially continuous

regenerated cellulosic fibers.

[0047] The images of Fig. 2 and 3 have been taken with an electron microscope Thermo Fisher Scientific - Quanta 450. The depicted surface areas are identical in both Fig. 2 and 3 and each have a dimension of about $800\mu\text{m} \times 550\mu\text{m}$.

[0048] Fig. 2 shows the structure of a nonwoven layer of rather fine substantially continuous regenerated cellulosic fibers. The picture was taken from a piece of a nonwoven layer herein designated as "Sample A". The fiber diameters are mostly ranging from about $2\mu\text{m}$ to about $8\mu\text{m}$, wherein most of the fibers are in a lower range of about $2\mu\text{m}$ to $4\mu\text{m}$ and only few of the fibers are stronger than that. Several bonding sites can be seen where different fibers have bonded to form nodes and also some bigger interconnected structures are to be identified. Nonetheless, the amount of merging and interfiber-bonding was kept rather low during production so that the route of the single fibers can be clearly seen in most parts of the nonwoven. The functional interaction of rather strong fibers on one hand and very fine fibers on the other hand in one nonwoven material in connection with the bonding sites provides for a stable porous network. Despite a rather high porosity, the structure of the nonwoven layer shown in Fig. 2 appears dense and compact. The dense appearance is mostly due to the uniform pore-size distribution that can be reached with the solution blown process. It can also be seen that especially the stronger fibers are often merged to other fibers by filament bonding, while the thinner fibers show fewer bonding sites.

[0049] Based on an assessment of the results of tests performed by the applicant (see also examples herein below) the optimal values for the porosity, the specific pore volume and the median pore size are thought to be found in the following ranges: A porosity ranging from 50 % to 90 %, preferably from 80 % to 90 %. A specific pore volume ranging from $2\text{cm}^3/\text{g}$ to $5\text{cm}^3/\text{g}$, preferably from $3\text{cm}^3/\text{g}$ to $4\text{cm}^3/\text{g}$. A median pore size ranging from $50\mu\text{m}$ to $120\mu\text{m}$, preferably from $80\mu\text{m}$ to $100\mu\text{m}$.

[0050] Fig. 3 shows a picture of a nonwoven layer according to the present disclosure having a coarser structure than the one shown in Fig. 2. The picture was taken from a piece of a nonwoven layer herein designated as "Sample B". Most fibers in the nonwoven layer shown in Fig. 3 have diameters ranging from about $2\mu\text{m}$ to about $8\mu\text{m}$, but in this case many of the fibers are in the higher range of about $4\mu\text{m}$ to about $8\mu\text{m}$. The structure of Sample B is less dense compared to Sample A, which results in a higher mean pore size. During production, a higher amount of inter-fiber bonding was allowed to take place. This results in a rather coarse and stable nonwoven layer, generally having larger pore sizes. Also the fibers show a strong filament bonding at many bonding sites which leads to bonded structures that are significantly broader than the single fibers and appear in the picture as nodes or even extensive lumps. Nonetheless, also in this case the nonwoven layer was produced to have a very uniform pore-size distribution.

[0051] The inventors noticed that, according to the teachings disclosed herein, nonwovens can be produced that have remarkable wicking properties already at very low basis weight and a rather thin thickness. The wicking properties can be assessed by either the wicking rate (i.e. the distance that a liquid travelled vertically upwards along the fabric in a given time) or the wicking time (i.e. the time it takes for a liquid to reach a specified distance). For example, in the context of nonwovens that are used as a fluid transporting layer in a lateral flow assay, given the usual length of such fluid transporting layers, the wicking time over a distance of 40 mm is a good quality indicating factor and should be as short as possible.

[0052] It has to be noted that with the solution-blown process the nonwoven layers can be produced with a very high degree of homogeneity, which means that the pore size distribution and the filament diameter distribution does not deviate much across the whole extension of the nonwoven layer. This makes the resulting quality of the nonwoven layer highly reproducible and the production parameter can be easily tailored to the specific needs. The nonwoven layer is mostly free of anomalies, such as excessively large pores or even holes. Such anomalies can often be seen in common nonwoven materials, for example due to a hydroentanglement treatment.

[0053] In the solution blown process several parameter can be adapted to change the resulting nonwoven layer according to the specific needs.

[0054] For example, the viscosity of the spinning solution can be altered. A higher viscosity generally leads to thicker fibers and also the coagulation speed changes. The viscosity has to be within the acceptable parameters of the spinneret. The viscosity also has effects on the tensile strength and the brittleness of the fibers.

[0055] By changing the spinneret arrangement (i.e. the arrangement, the number of the spinning nozzles and the distance between the nozzles), the size, particularly the width and the thickness of the nonwoven layer can be controlled. The spinneret dimensions (i.e. the nozzle diameter and form and/or the distance between single nozzles) influence the homogeneity of the nonwoven layer (amongst several other effects).

[0056] Another important parameter that has an effect on numerous properties is the extrusion speed. It directly alters the basis weight of the nonwoven layer, but also has effects on other factors, such as the coagulation or the multibonding of the fibers.

[0057] Also, the extension airflow can be adjusted, which (inter alia) alters the fiber stretch and the entanglement of the fibers.

[0058] By changing the intensity of the coagulation spray, the coagulation of the fibers in the air-gap (i.e. before the formation of the nonwoven layer) can be controlled. This has a huge effect on the formation of merging sites between

the fibers. A low amount of coagulation spray leaves the fibers in a less coagulated state so that they are still "sticky" at the time of formation of the nonwoven layer, which induces a high amount of interbonding sites.

[0059] The air gap distance between the spinneret, where the fibers are extruded, and the foraminous support, where the fibers are collected in form of the nonwoven layer, has an effect on the entanglement of the fibers. For example, the fibers have more time to swirl and entangle with adjacent fibers when the air gap is increased, which leads to a high degree of entanglement. Also the coagulation is influenced by the air gap distance. On the other hand, an oversized air gap could have a negative impact on the homogeneity of the nonwoven layer.

[0060] The speed of the foraminous support mainly alters the basis weight of the nonwoven layer but also has several effects on the web-formation.

[0061] Further, the post processing of the nonwoven layer (washing, squeezing, use of finishing agent, etc.) can be used to alter the quality and properties of the nonwoven layer.

[0062] By a systematic alteration of these parameters, the person skilled in the art, who is aware of the teachings disclosed herein, is able to find optimized process control settings to reach a specific property in the resulting nonwoven layer by routine experimentation and analysis.

[0063] The current inventors found out that the main parameters for controlling the wicking rate of a so produced nonwoven layer are the filament stretch through stretching air pressure (which also affects the diameter distribution of the filaments in the nonwoven layer) and the amount of coagulation liquid used to coagulate the filaments in the air gap after the spinneret.

[0064] A high filament stretch through high stretching air pressure at the spinneret creates fine filaments. To coagulate the fine filaments, a high amount of coagulation liquid is needed. The finer the filaments are, the more coagulation liquid is needed. Finer filaments generally go in hand with better wicking properties. Therefore, the wicking properties can be improved (i.e. higher wicking rate and lower wicking time) by raising the stretching air pressure and the amount of coagulation liquid.

[0065] The nonwoven layers that are made by the solution blown process can be produced 100 % biodegradable or even compostable which, for example, allows for the production of ecological lateral flow assays. By also using biodegradable materials for the production of the housing and the other parts of the lateral flow assay a completely biodegradable or even compostable lateral flow assay can be produced.

Examples

[0066] It should be noticed that for all measurements and parameters described and disclosed herein, the samples were conditioned at 23°C ($\pm 2^\circ\text{C}$) and 50% ($\pm 5\%$) relative humidity for 24 hours, unless specifically stated otherwise.

1. Sample production

[0067] Two products comprising a nonwoven layer were manufactured by the applicant using the solution blown process described herein. The products were designed to produce a highly porous 3-dimensional web ("Sample A and Sample B"). The basis weight of the nonwovens layer of Sample A was adjusted to 70 g/m² and the basis weight of the nonwoven layer of Sample B was adjusted to 68 g/m². By precise adjustment of the process air conditions, the solution blown nonwovens of the samples were created to give a high relative surface area whilst maintaining a product surface that is virtually free of mechanical defects like irregularly large holes.

[0068] For Sample A a high amount of stretching air pressure and coagulation liquid was set to produce a nonwoven layer with a very fine fiber structure. To assess the effects of changing these parameters, Sample B was produced with a lower amount of stretching air pressure and coagulation liquid. The stretching air pressure of Sample A was about 2 times higher and the coagulation water flow was about 1.5 times higher compared to Sample B.

[0069] It should be noted that the production of a nonwoven layer with very fine fiber diameters (such as in Sample A) is generally more expensive. Therefore, optimal settings will probably be found in a range where the requested wicking properties can be reached at minimal costs. The person skilled in the art, being aware of the teachings disclosed herein, is able to find such settings by standard experimentation without undue burden.

2. Pore analysis

[0070] The pore size distribution of Sample A was measured via Hg-Porosimetry according to ISO 15901-1:2016, using a Quantachrome Poremaster 60-GT, 3P Instruments GmbH & Co KG. The theoretical basis for the method is the so called Washburn equation, which represents the relation between pore filling (intrusion) and pore emptying (extrusion) as a function of the applied pressure through a non compressible, non-wetting liquid (Mercury). The porosity is calculated according to the following formula:

$$\text{Porosity} = \text{Specific pore volume} / \text{Material density} \times 100\%$$

[0071] The nonwoven layer according to Sample A showed a uniform pore size distribution with a median pore diameter at 93 μ m. The overall nonwoven thickness was measured to be 490 μ m, which indicates the average pore size constituting almost 20% of the overall nonwoven caliper. Sample A had a specific pore volume of 3.731 cm³/g, a raw density of 0,23 g/cm³ and a porosity of 85.5 %.

[0072] As a result of the measurement, a normalized volume curve is obtained, where the intruded volume is shown as a function of pore size. Since larger pores are intruded prior to smaller pores, the axis of ordinates shows the pores size decreasing from left to right. The pore size distribution curve is being calculated by differentiation of a normalized volume graph. The result of the pore size distribution measurement is depicted in Fig. 4. The axis of abscissas refers to the pore size (i.e. the diameter) on a logarithmical scale, the axis of ordinates shows the relative frequency of a specific pore size.

[0073] The results shown in Fig. 4 evidence that the average pore size of Sample A is considerably larger (about 4 times) than for instance of graphical paper. The pore size in paper products is, for example, described in "The pore radius distribution in paper. Part I: The effect of formation and grammage", Dodson, C.T.J., Handley, Am Oba, Y, Sampson, W. Appita Journal, 2002, 56.

[0074] The pore analysis was only performed for Sample A.

3. Wicking test

[0075] Samples A and B were subjected to a liquid uptake speed tests ("nonwoven absorption") according to Harmonized Nonwovens Standard Procedure NWSP 010.1.R0 (15) [EN]. The results were compared with a standard commercial laboratory paper sample ("comparison") which were tested according to the same protocol. The wicking rates after 300 s were measured for the samples and the comparison. Also, for the Samples A and B the wicking rates after 10 s, 30 s and 60 s were measured. Further, the time required to pass a mark that was arranged 40mm above the water surface (i.e. the "40 mm wicking time") was also recorded. It is to be noted that the measurement of the 40 mm wicking time is not explicitly described in NWSP 010.1.R0, but can be easily implemented according to this protocol.

[0076] The measurements for Sample A and B were done in machine direction (MD) and in cross direction (CD).

[0077] Results of the wicking tests are shown in Table 1 below.

Table 1 - wicking test

Sample	Wicking rate [mm]				Wicking time [s/40 mm]
	10s	30s	60s	300s	
Comparison				66	82
Sample A (MD)	44	65	87	148	8
Sample A (CD)	41	62	80	129	10
Sample B (MD)	37	61	80	150	12
Sample B (CD)	33	51	69	128	16

[0078] The results show that the wicking times of the tested samples A and B are about 5 to 10 times faster than the wicking time of conventional laboratory paper. Also, the wicking rate at 300 s in CD is about twice the amount of the laboratory paper and the wicking rate at 300 s in MD is even better.

[0079] A comparison of the test results in MD and CD suggest that the fluid migration speed is very similar in both directions of the nonwoven material.

4. Summary

[0080] The tested nonwoven product showed remarkable and surprisingly good wicking properties, both in machine direction and cross-direction. Due to its microstructure, the product exhibits a fast wicking performance and time-constant fluid transportation capabilities. This allows, *inter alia*, for the use of the product as a fluid transporting layer of lateral flow assays, where high and reliable wicking rates are desired. Consequently, the innovation of the novel nonwoven layer according to the present disclosure enables the development of fast, specific and reliable new diagnostic tests.

[0081] The wicking time of the nonwoven layer can be adjusted to a wicking time of between 5 and 50 s/40mm,

preferably between 8 and 20 s/40mm by adjusting the stretching air pressure and the amount of coagulation liquid, wherein an increase in air pressure and/or coagulation liquid reduces the wicking time of the nonwoven layer.

[0082] The use of this completely cellulosic material obviates the need for ecologically problematic special materials comprising glass fibers or synthetic polymer fibers.

5

Reference numbers:

[0083]

- 10 lateral flow assay 1
- housing 2
- upper side 3
- sample port 4
- display port 5
- 15 result display port 6
- test display port 7
- fluid transporting layer 8
- sample pad 9
- conjugation pad 10
- 20 test membrane 11
- absorbent pad 12
- test result line 13
- control line 14

25

Claims

1. Nonwoven layer comprising a network of substantially continuous regenerated cellulosic fibers, **characterized in that** the nonwoven layer has a wicking time of between 5 and 50 s/40mm, preferably between 8 and 20 s/40mm, wherein the wicking time is determined by measuring the time it takes for the water to reach a level of 40 mm above liquid surface in a test arrangement according to Harmonized Nonwovens Standard Procedure NWSP 010.1.R0 (15).
2. Nonwoven layer according to Claim 1, having a basis weight of between 15 g/m² and 200 g/m², preferably between 20 g/m² and 100 g/m².
3. Nonwoven layer according to Claim 1 or 2, having a porosity of between 50 % and 90 %, preferably between 80 and 90%.
4. Nonwoven layer according to any of the Claims 1 to 3, having a specific pore volume of between about 2 cm³/g and about 5 cm³/g, preferably between about 3 cm³/g and about 4 cm³/g.
5. Nonwoven layer according to any of the Claims 1 to 5, having a median pore size of between 50 and 120 μm, preferably between 80 and 100 μm.
6. Nonwoven layer according to any of the Claims 1 to 5, wherein the fibers in the nonwoven layer are finish free.
7. Nonwoven layer according to any of the Claims 1 to 6, wherein the nonwoven layer is essentially free of copper and/or nickel.
8. Nonwoven layer according to any of the Claims 1 to 7, wherein at least a part of the nonwoven layer is directly manufactured from lyocell spinning solution in a solution blown process.
9. Nonwoven layer according to any of the Claims 1 to 8, wherein the cellulosic fibers in the nonwoven layer are multibonded by merging, hydrogen bonding and/or physically intermingling.
10. Nonwoven layer according to any of the Claims 1 to 9, wherein the fibers of the nonwoven layer have diameters ranging from 1 μm to 250 μm, preferably from 2 μm to 75 μm.

55

EP 4 293 148 A1

11. Use of a nonwoven layer according to any of the Claims 1 to 10 for the production of a sample fluid transporting layer in a lateral flow assay.

5 12. Lateral flow assay comprising a housing with at least one sample port and at least one display port and at least one sample fluid transporting layer, **characterized in that** the at least one sample fluid transporting layer comprises at least one nonwoven layer according to any of the Claims 1 to 10.

10 13. Lateral flow assay according to Claim 12, comprising at least one fluid transporting layer, the fluid transporting layer comprising at least one of a sample pad, a conjugate pad, a test membrane and/or an absorbent pad, wherein at least one of the sample pad, the conjugate pad, the test membrane and/or the absorbent pad comprises at least one nonwoven layer according to any of the Claims 1 to 11.

15

20

25

30

35

40

45

50

55

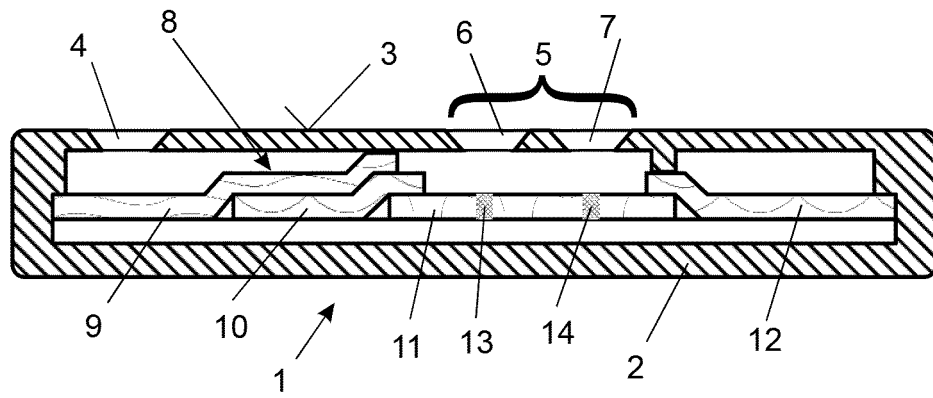


Fig. 1

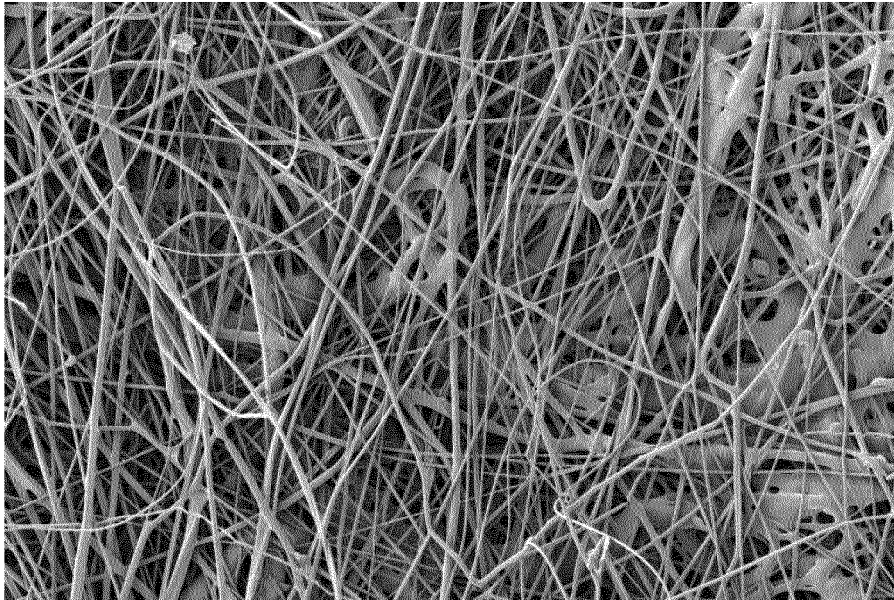


Fig. 2

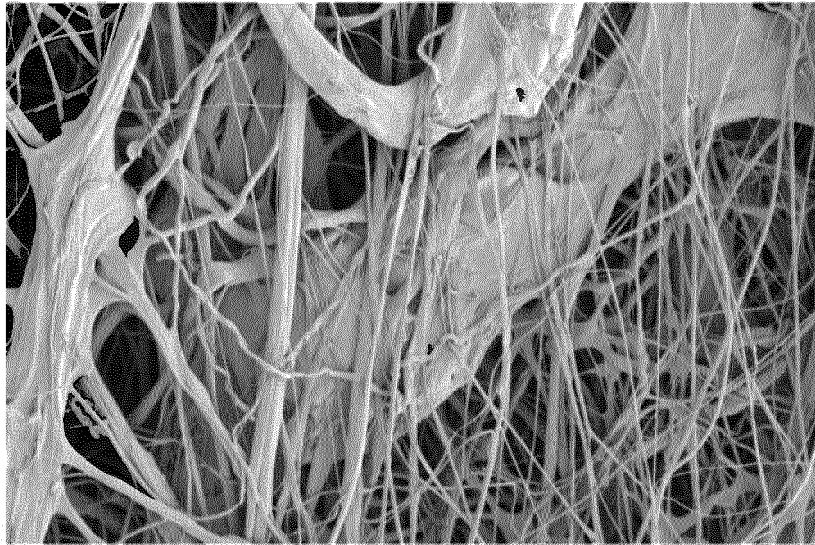


Fig. 3

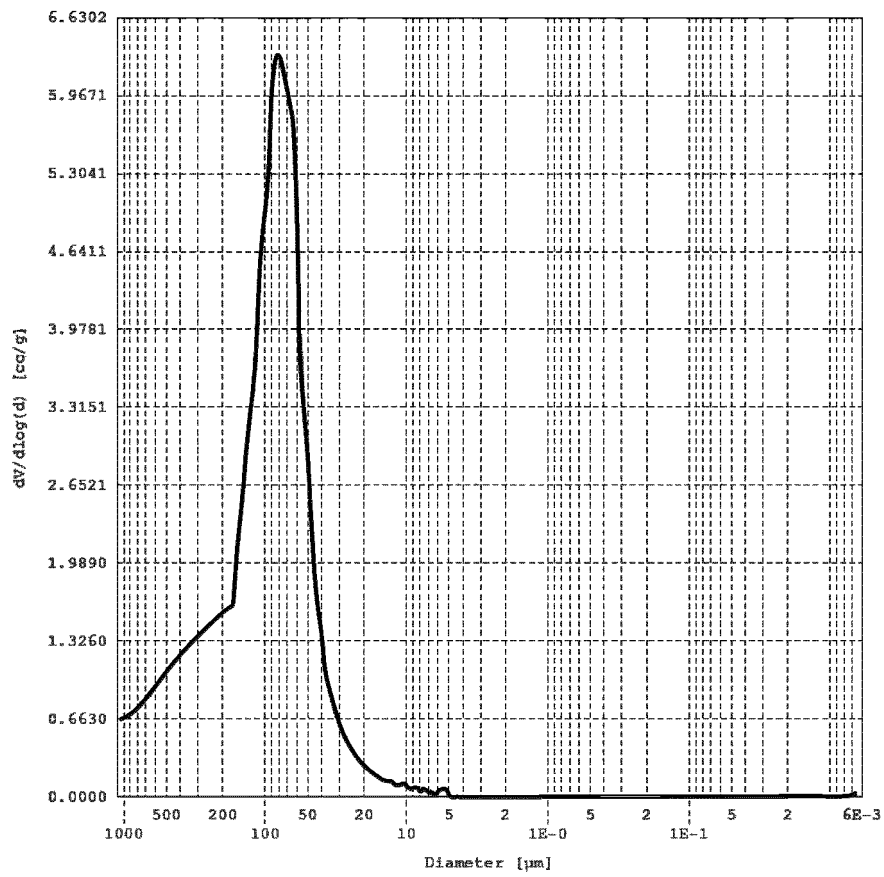


Fig. 4



EUROPEAN SEARCH REPORT

Application Number
EP 22 17 9266

5

10

15

20

25

30

35

40

45

50

55

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X, D A	WO 2018/184038 A1 (CHEMIEFASER LENZING AG [AT]) 11 October 2018 (2018-10-11) * page 2, line 19 - line 30 * * page 6, line 11 - line 32 * * page 13, line 16 - page 16, line 12; examples 1, 2; tables 1, 2 * -----	1-10 11-13	INV. D04H3/013 G01N33/543
	A JP 2017 215284 A (ASAHI KASEI CORP) 7 December 2017 (2017-12-07) * paragraph [0035] - paragraph [0036] * * paragraph [0060] * -----	1-13	
			TECHNICAL FIELDS SEARCHED (IPC)
			D04H G01N
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 23 November 2022	Examiner Demay, Stéphane
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

1
EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 22 17 9266

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

23-11-2022

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2018184038 A1	11-10-2018	BR 112019020010 A2	28-04-2020
		CN 110506139 A	26-11-2019
		EP 3607123 A1	12-02-2020
		JP 7102662 B2	20-07-2022
		JP 2020521061 A	16-07-2020
		KR 20190127975 A	13-11-2019
		TW 201843368 A	16-12-2018
		US 2021101362 A1	08-04-2021
		WO 2018184038 A1	11-10-2018

JP 2017215284 A	07-12-2017	JP 6754618 B2	16-09-2020
		JP 2017215284 A	07-12-2017

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- EP 1093536 B1 [0003]
- EP 2013390 B1 [0003]
- EP 2212456 B1 [0003]
- WO 2007124521 A1 [0008]
- WO 2018071928 A1 [0008]
- WO 2018184941 A1 [0008]
- WO 2020016296 A1 [0008]
- WO 2018184038 A [0028]
- WO 2018184932 A [0028]

Non-patent literature cited in the description

- **DODSON, C.T.J. ; HANDLEY ; AM OBA ; Y, SAMP-SON.** The pore radius distribution in paper. Part I: The effect of formation and grammage. *W. Appita Journal*, 2002, vol. 56 [0073]