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(54) PERSONAL PROTECTIVE EQUIPMENT AGAINST PATHOGENIC MICROORGANISMS AND RELATED PRODUCTION METHOD

(57) Personal protective equipment (100) against pathogenic microorganisms to protect the airways of a user, comprising:
- a first layer (101) and a last layer (102) in woven and stable fabric;
- at least a further layer (103) made of fabric, said at least a further layer (103) being interposed between the first layer (101) and the last layer (102) and superficially covered with zeolite powder.

The zeolite powder is obtained from synthetic zeolites type 3A and 4A or natural clinoptilolite.

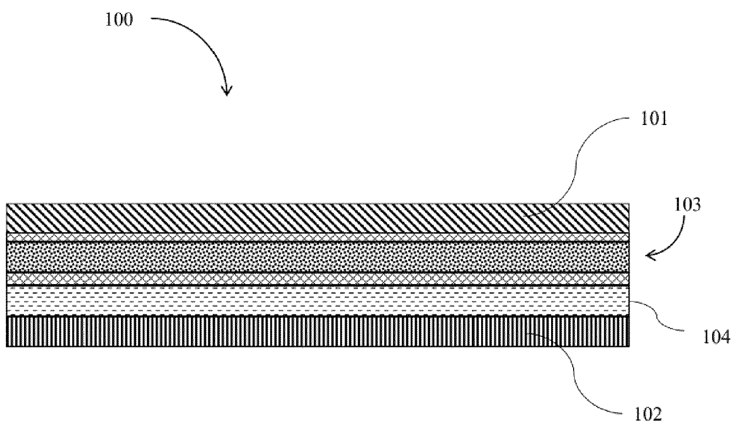

Fig.1

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Description

[0001] The present invention relates to the technical field of personal protective equipment against pathogenic microorganisms and, in particular, of wearable face masks, in correspondence of the nose and mouth, for the protection of airways from pathogenic microorganisms and even more particularly for the protection from viruses, more particularly those of the coronavirus (CoV) family.

[0002] Many pathogens are airborne, causing viral infections, and bacterial infections. It is therefore particularly important to protect the main access routes to the airways from pathogenic microorganisms, namely the nose and mouth. As is known, an epidemic caused by the SARS-CoV-2 virus, belonging to the coronavirus family, is currently underway, which includes strains at the origin of both the common cold and acute respiratory distress syndrome (SARS). At present, there are no specific therapies with respect to infections caused by some pathogenic microorganisms, such as in particular those related to new coronavirus and its strains. The latter have dimensions of 100-150 nanometers and their transmission occurs mainly by air through secretions containing pathogens, which are emitted during respiration, which can reach dimensions of a few microns in the case of aerosol formation. Massive measures of social distancing have been defined as the only way to reduce the chain of spread of airborne pathogens and, in particular, for coronaviruses. In the clinical and community setting, hand and surface hygiene through alcohol-based detergents is highly recommended, in addition to other behaviors defined as correct. The situation is even more complex in clinical contexts, where the sources of contagion are multiple. Personal protective equipment (PPE), including face masks, gloves, goggles and disposable gowns, are among the main preventive protection measures against sources of contagion. The guidelines of the World Health Organization (WHO) suggest a differentiated use of face masks, based on the degree of exposure and the type of pathogen.

[0003] For individual protection from pathogens, and in particular from pathogens transmissible by air, protective masks are currently used, divided into: face masks, surgical face masks, and filtering facials. The latter are further classified at the European level based on the degree of protection in FFP1, FFP2 and FFP3.

[0004] Among the protective equipment against airborne pathogens currently in use, multilayer face masks, such as surgical ones, are formed by three or more layers of TNT or non-woven fabric, consisting of polyester or polypropylene fibers. Typically, the layer exposed to the outside is made using spun bond technology with possible hydrophobic treatment. The intermediate layer is made of TNT produced with melt blown technology and made of 1-3 micron diameter microfibres, in polyester polypropylene with filtering activity. A third layer is in contact with the face of a user and protects the skin from the filtering layer. Although the multilayer face masks are effective because they have a quantifiable and reliable filtering capacity towards the outside, they do not guarantee high protection against a pathogen that comes from the outside, due to the poor adherence to the face and their inability to retain fine particles and very fine, such as aerosol type.

[0005] Personal protective equipment such as filtering facepieces defined according to the European standards FFP1, FFP2, FFP3, are designed for industrial use to protect against dust, fumes and mists and are also used in the health sector, particularly in infectious disease wards, since the material that constitutes them has a high protective capacity to and from the external environment. The filtering layer, usually in fabric made with melt blown technology, acts mechanically for particles up to a few microns in diameter. For even smaller particles, the most important effect is the electrostatic one: the fibers electrostatically capture the fine particles, blocking them.

[0006] In order to improve the protective capacity of a PPE such as face masks, equipment with improved capacity have been developed.

[0007] An example of an improved protection equipment is described in the Portuguese patent application PT2162223T which relates in particular to a face mask comprising a portion that covers the nose and mouth made in at least three layers. At least one of the layers comprises a fabric which includes a substance capable of chemically binding a pathogen. The fabric, in addition, comprises at least one polyvalent metal ion or a metal salt, and at least one of the layers provides a thermoformable fabric.

[0008] Studies and industrial applications are also known in which zeolite is used as a filter medium for particulate matter and atmospheric pollutants (NOx, ozone, PM and cesium radioisotopes).

[0009] However, although advantageous under various aspects, currently known face masks do not allow to reduce the proliferation of pathogenic microorganisms, and in particular of the CoV family and even more particularly of SARS-CoV-2 and airway pathogens, and at the same time guarantee a good filtering capacity, good comfort in use and a low cost.

[0010] The purpose of the present invention is to provide an individual protection equipment or a face mask that includes a layer or a plurality of layers capable of increasing its protective capacity from pathogenic microorganisms and comfort for the user.

[0011] Furthermore, the object of the present invention is to provide an individual protection equipment or a face mask capable of reducing the proliferative activity of pathogenic microorganisms and in particular of the SARS-CoV-2 virus, guaranteeing optimal protective properties at a low equipment cost and having, therefore, characteristics such as to overcome the limits of currently known protection equipment.

[0012] Still, the object of the present invention is to provide an individual protective equipment or face mask that allows to reduce, during use, the accumulation of CO2 generated during breathing.

[0013] According to the present invention, a personal protective equipment against pathogenic microorganisms, or protective face mask, as defined in claim 1, is provided.

[0014] According to the present invention, a production method of the personal protective equipment against pathogenic microorganisms is also provided, as defined in claim 7.

[0015] For a better understanding of the present invention, a preferred embodiment is now described, purely by way of non-limiting example, with reference to the attached drawings, in which:

- Figure 1 shows a schematic sectional view of personal protective equipment against pathogenic microorganisms, according to the invention;
- Figure 2 is a perspective and detailed view of the personal protective equipment against pathogenic microorganisms, according to the invention;
- Figure 3 shows a microscope view of a layer of the personal protective equipment against pathogenic microorganisms or face mask on which zeolite powder is applied, according to the invention;
- Figure 4 shows a graph of the adsorption capacity of water molecules in environmental conditions after exposure to an air flow with high relative humidity for zeolite 3A, 4A and clinoptilolite, according to the invention;
- Figures 5a-5b show scanning electron microscope images at different magnifications of the layers composing a surgical mask according to prior art, and of a zeolite-covered weft obtained by spreading and pressing zeolite powder onto a melt blown polypropylene layer of a personal protective equipment against pathogenic microorganisms, according to the invention;
- figure 6 shows antiproliferation effect activity of a personal protective equipment against pathogenic microorganisms, compared to a bacteria, according to the invention;
- figure 7 shows a detail view of a personal protective equipment against pathogenic microorganisms, according to the invention.

[0016] With reference to Figure 1 and Figure 2, the personal protective equipment 100 against pathogenic microorganisms according to the invention consists of a respiratory protection equipment, such as a disposable face mask or more particularly a multilayer surgical face mask which by way of an example is shown in figure 2, which can be worn on the nose and mouth of a user.

[0017] The individual protective equipment 100 comprises a first layer 101 and a last layer 102 made of fabric, preferably of a soft and stable woven fabric, even more preferably of TNT. The personal protective equipment 100 also comprises at least one further layer 103 interposed between the first 101 and the last layer 102, said further layer 103 being filled with a layer of zeolite.

[0018] Among the nanomaterials, zeolite is a natural or synthetic crystalline aluminosilicate with a defined crystalline structure and porosity. The pores and channels of the zeolite are uniform with dimensions ranging from 3 to 12 Å. The applications of zeolite as a molecular sieve, ion exchanger or for molecular adsorption have been extensively studied. In the present invention, advantageously, the use of zeolite allows to exploit in addition to the absorbing characteristics, also the ability to reduce the proliferative activity of pathogenic microorganisms. Furthermore, advantageously, the zeolite powder applied to the further layer 103 of the protection equipment 100 allows to increase the absorption capacity of the breath at high humidity and high CO2 content, obtaining optimal comfort for the wearer. In particular by reducing the phenomena of visual fogging, even more particularly the phenomena of CO2 accumulation, such as respiratory acidosis.

[0019] According to the present invention, the zeolite powder applied to at least one further layer 103 and intermediate layer of the individual protective equipment 100 is zeolite powder obtained from synthetic and natural zeolites having non-toxic characteristics.

[0020] According to one aspect of the invention, the zeolite powder is obtained from synthetic 3A and 4A zeolites having a particle size greater than or equal to 5 microns. Advantageously, the zeolite powder is sieved so that the particle size is suitable for eliminating the dispersion of fine powders outside the face mask, this optimal particle size is the one with a diameter greater than or equal to 1-2 microns, more specifically 3-4 microns, even more particularly greater than or equal to 5 microns.

[0021] According to another aspect of the invention, the zeolite powder applied to at least one further layer 103 of the protection equipment 100 comprises clinoptilolite powder, i.e. natural zeolite free of organic material, with a particle size such as to eliminate the dispersion of fine powders used in the outside of the face mask, or even synthetic zeolite 3A or 4A. The preferred particle size is greater than or equal to 5 microns.

[0022] The further layer on which the zeolite powder is applied according to the invention has a morphology, shown in figure 3, the zeolite powder (3A and 4A) appears as a set of cubic crystals.

[0023] According to one aspect of the invention, the production process of the personal protective equipment 100 against pathogenic microorganisms includes the following steps of:

- spreading a fabric layer, preferably fine-meshed fabric with dimensions, preferably 17x12 cm, for example with 10 gr of zeolite powder or even lower, even more preferably with a quantity of zeolite powder comprised between 2 grams and 10 grams, preferably comprised between 2 g and 5g, to form the further intermediate layer of the protection equipment

100;

- overlaying a layer of fabric on the one previously spread with zeolite powder;
- using the "powder compaction" technique to create thin layers in which the fabric matrix gives greater mechanical stability;
- fixing the adjunctive meltblown polypropylene layer and weld it together with other layers of the protective device;
- making a multilayer face protection mask having at least a first layer 101, a last layer 102 and a further intermediate layer 103 consisting of layer impregnated with zeolite powder.

[0024] According to an aspect of the invention, in the production process of the protective equipment 100 the step of making a multilayer face protective mask consists in applying, to known face masks, the further layer 103 containing zeolite powder.

[0025] According to an aspect of the invention, as shown in Figure 1, the personal protective equipment 100, or protective mask, is constituted by a first layer 101, facing outwards during use, of bound polypropylene (hydrophobic yarn), an intermediate filter layer 104 (made of melt blown polypropylene) and a last internal layer 102 of bonded polypropylene (soft yarn, adsorbent).

[0026] As shown in figure 1 and in figure 2 the further layer 103 impregnated with zeolite is firmly confined between the first external layer 101 and the filtering layer 104, then the mask is sealed again obtaining an active layer, preferably of 200 cm^2, even more preferably greater than 200 cm^2.

[0027] According to an aspect of the invention, the zeolite present in the protective equipment 100 is modified with metal ions selected from zinc, silver, copper ions. Zeolite powder is composed of nanoporous crystals characterized by the presence of metal ions in the structure. One of the main characteristics of zeolite is its ability to work as an ion exchanger, replacing the original metal ion with others present in the environment.

[0028] Advantageously, the effect of zeolite suspensions modified with silver, copper and zinc ions in PBS solution has an effect against pathogenic microorganisms such as in particular those of the coronavirus family.

[0029] The Applicant has carried out comparative experimental tests on the adsorption and proliferation capacity of pathogenic microorganisms of the personal protective equipment according to the invention. The nanoporous material was analyzed by scanning electron microscopy (SEM) and Fourier transform infrared spectroscopy (FT-IR). Furthermore, spectroscopic analysis was used to study the uptake of endogenous non-coding RNA (miRNA) molecules and its interaction with the nanoporous layer. Furthermore, the adsorption capacity of water and CO2 molecules was evaluated by thermogravimetric analysis of zeolite powder.

[0030] In order to study the absorption capacity of the zeolite powder used, the adsorption of single-stranded DNA (22 nucleotides) was evaluated by FT-IR spectroscopy. The 3A and 4A zeolite pellets were obtained by means of a PW 10 H (50 kN) heated press. The gravimetric analysis performed on the pellet is shown in Figure 3.

[0031] The water adsorption isotherms of zeolite 3A, 4A and clinoptilolite are similar, with an absorption capacity after 1 h comprised between 10 and 20% by weight. By means of the cited experimental tests, the Applicant has shown that the use of powder instead of pellets leads to a greater adsorption capacity, which can be higher than 20% by weight.

[0032] A drop of water was deposited on each pellet, with a volume of 10 μL and a miRNA concentration of 100 pmol / μL. After deposition, the sample was washed in deionized water and dried under nitrogen flow. The infrared analysis showed the presence of the characteristic adsorption band of the oligonucleotides at about 1160-10 cm^{-1} and 832-10 cm^{-1}, which do not appear on a control sample not exposed to miRNA. Furthermore, the electrostatic and Van Der Waals interaction between the zeolite and the biomolecules, characteristic of the structure of the zeolite, can predict a surface adsorption of the molecules.

[0033] The protective equipment according to the invention is effective for the protection of numerous pathogens transmissible by air. In particular, the effectiveness against SARS-CoV-2 was evaluated.

[0034] The SARS-CoV-2 virus was studied by cryogenic electron microscopy, showing an approximately spherical shape with a diameter between 80 nm and 120 nm. The proteins called "spike" present on the surface can be seen as molecular hooks with a length of 23 nm, a stem of 4 nm and a head of approximately 7 nm. The use of a layer containing powdered zeolite according to the invention has shown an inhibitory effect in viral proliferation. In addition, the molecular hooks and the very small dimensions can favor electrostatic interaction with the structure of the zeolite, allowing a surface bond that further reduces the risk of spreading the virus.

[0035] The additional intermediate layer containing zeolite, applied to a surgical face mask or other airway protective equipment, has been shown to be active in reducing exhaled moisture, improving comfort during use and also in reducing the activity of the virus and its spread in the environment.

[0036] As shown in figure 5a, the physical barrier is realized using multiple layers with a different weft and fabrics. Denser fibers characterize the filtering layer of a surgical mask (part b) and are suitable for blocking the smallest airborne particles, while inner and outer layers have wider weft and possess hydrophobic characteristics (Figure 5, outer layer, part a) and give greater wearability even for long periods of use (inner layer, part c). In particular figure 5a shows scanning electron microscopyimages at different magnifications of the layers composing a surgical mask which include an outer hydrophobic polypropylene layer (a) a filtering polypropylene layers (b) and an inner soft polypropylene layer (c).

[0037] Advantageously, the barrier effect is greater in the invention than in a mask according to the prior art.

[0038] Figure 5b shows adjunctive meltblown polypropylene layer impregnated with zeolite (i.e. part A) and the shape of few representative powder grains in the insect (part b). As a result of spreading and pressing zeolite powder onto the meltblown polypropylene layer, a zeolite-covered weft was obtained, as representatively reported in Figure 5b. Zeolite powder appears as a set of cubical crystals, while clinoptilolite powder is characterized by a more irregular geometry.

[0039] Figure 6, shows the antiproliferative effect of the powder according to the invention compared to a bacterium (for example Escherichia coli). The powder was put in solution with the bacterium and the proliferation of this bacterium was evaluated optically (optical density, OD at 600 nm), as shown in figure 6 in a time interval of 6 hours, using two levels of powder concentration. Said time interval being compatible with the time of use of a surgical mask.

[0040] Figure 6b shows this the antiproliferative effect by comparing the variation in optical density in each solution used which is an index of how much the bacteria are proliferating. The figure 6b shows that in the control solution and in low concentration clinoptilolite there is a significant increase in optical density (proliferation) over the time considered. This does not happen contrary to solutions containing clinoptilolite at a higher concentration and zeolite 3A (at both concentrations) and 4A. This data shows an antiproliferative effect during contact between the pathogen and the powder, said effect being beneficial in the case of the presence of the pathogen on the protective device according to the invention. Furthermore, according to the invention, the additional layer of material allows to confine the pathogen and avoid contact with the airways.

[0041] According to an aspect of the invention, shown in Figure 7, the personal protective equipment (100) comprises a folded upper edge 120, folded towards the face of a user.

[0042] Advantageously, as pathogenic microorganisms can also have access to the body through the ocular ways (tears or eye contact with infected hands), and as the use of individual eye protection devices is mandatory in some environments, the folded upper edge 120 guarantees a better conveyance of the exhaled gas outwards (in accordance with the direction highlighted in figure 7), improving comfort, especially in the case of concomitant use of eye protection devices (for example eye masks, protective goggles). Advantageously, the folded upper edge 120, considerably reduces fogging phenomena by improving the conveyance of gases.

[0043] Advantageously, the personal protective equipment according to the invention contains biocompatible and non-toxic zeolite.

[0044] Advantageously, the individual protective equipment according to the invention comprises a non-invasive and easy-to-include filtering layer, incorporated with zeolite powder.

[0045] Advantageously, according to the invention, the zeolite incorporated in the protective equipment can be modified with the addition of metals, improving its characteristics and the contrast to pathogenic microorganisms.

[0046] Advantageously, the personal protective equipment according to the invention allows to reduce the proliferation activity of pathogenic microorganisms that adhere to the surface of the further layer 103 containing zeolite during breathing, even in the presence of exhaled gas.

[0047] Advantageously, the protection equipment according to the invention allows to reduce, during use, the accumulation of $CO2$ generated during breathing thanks to the $CO2$ adsorption capacity by the layer containing zeolite.

[0048] Advantageously, the personal protective equipment according to the invention guarantees a high level of safety, in particular higher than that of the individual protective equipment without the additional layer according to the invention.

[0049] Finally, the personal protective equipment according to the invention allows the absorption of humidity and $CO2$ due to exhalation, reducing, among other things, problems such as fogging of glasses, and respiratory acidosis and considerably improves comfort during the 'worn by a user.

[0050] Finally, it is clear that modifications and variations may be made to the individual protective equipment against pathogenic microorganisms and its production process here described and illustrated can be modified without thereby departing from the protective scope of the present invention, as defined in the attached claims.

Claims

1. Personal protective equipment (100) against pathogenic microorganisms to protect airways of a user, comprising:

- a first layer (101) and a last layer (102) in woven and stable fabric;
- at least a further layer (103) made of fabric, said at least a further layer (103) being interposed between the first layer (101) and the last layer (102) and superficially covered with zeolite powder;

characterized in that said zeolite powder is obtained from synthetic zeolites type 3A and 4A or natural clinoptilolite.

2. Personal protective equipment (100) according to claim 1, **characterized in that** said zeolite powder has grain size greater than or equal to 5 microns.

3. Personal protective equipment (100) according to claim 1, **characterized in that** said zeolite powder is made of pulverized non-toxic zeolites.

4. Personal protective equipment (100) according to claim 1, **characterized in that** said zeolite is modified with metal ions chosen from zinc, silver, copper ions.

5. Personal protective device (100) according to claim 1, **characterized in that** said first layer (101) turns outwards during use and is made of bonded polypropylene, said last layer (102) is made of polypropylene, and further comprises a central filtering layer (104) made in fusion-blown polypropylene, said intermediate further layer (103) on which zeolite powder is bound being firmly anchored between the first layer (101) and the filtering layer (104) .

6. Personal protective device (100) according to claim 1, **characterized in** comprising a folded upper edge (120), in use folded towards the face of a user.

7. Method for the production of the personal protective equipment (100) according to one of the preceding claims, consisting of the steps of:

- spreading two portions of fabric with zeolite powder confined in a further layer (103) of the personal protective equipment (100);
- superimposing a layer of fabric on the further layer (103) spread with zeolite powder;
- creating thin layers by means of "powder compaction" technique in which the fabric matrix gives greater mechanical stability;
- fixing the adjunctive meltblown polypropylene layer and weld it together with other layers of the protective device;
- providing a multilayer protective equipment having at least a first layer (101), a last layer (102) and a further layer (103) intermediate between them and consisting of a fabric spread with zeolite powder.

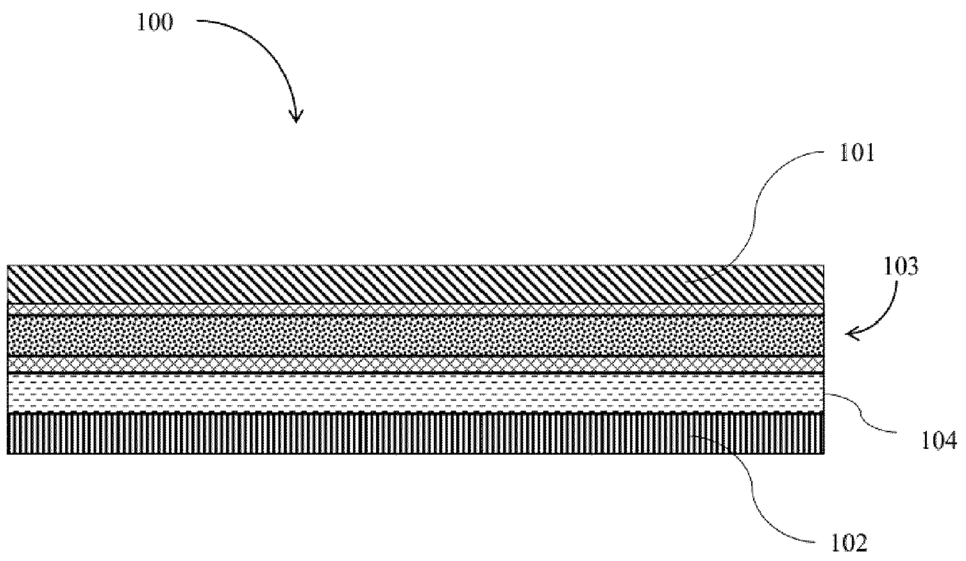

Fig.1

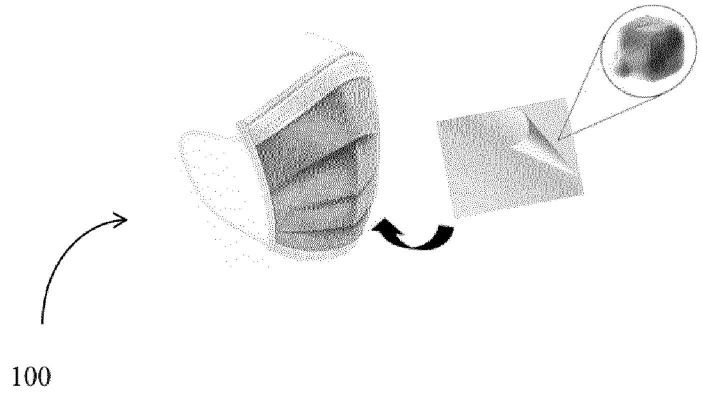

Fig.2

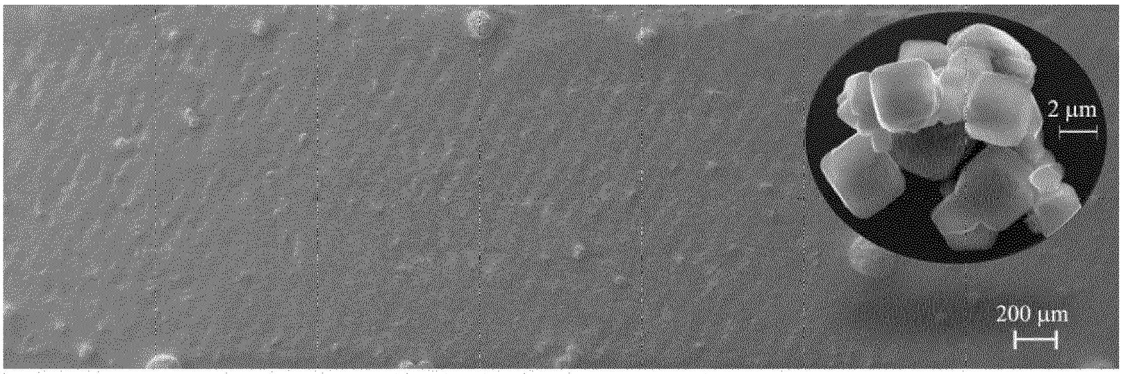

Fig.3

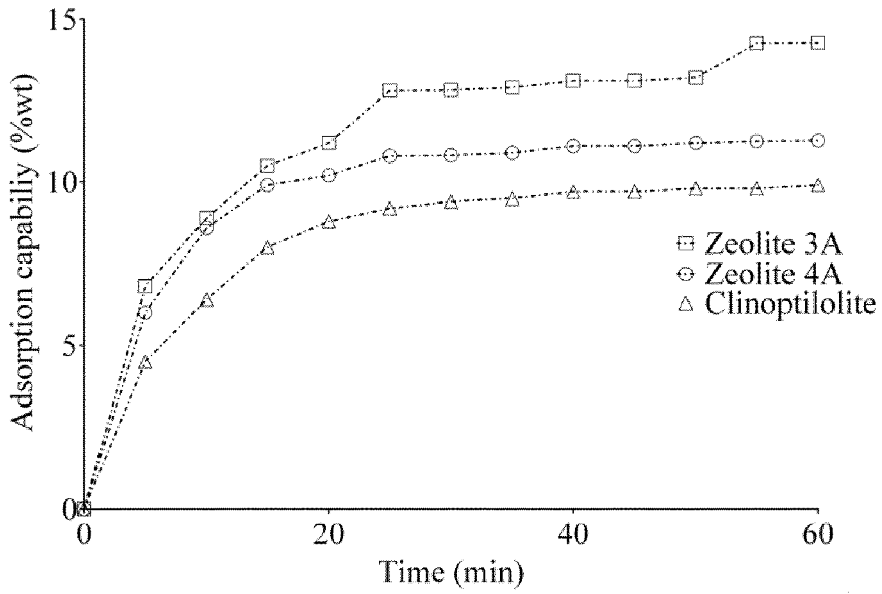
15
10
5
0
Adsorption capabiliy (%wt)
0
20
40
60
Time (min)
Zeolite 3A
Zeolite 4A
Clinoptilolite

Fig.4

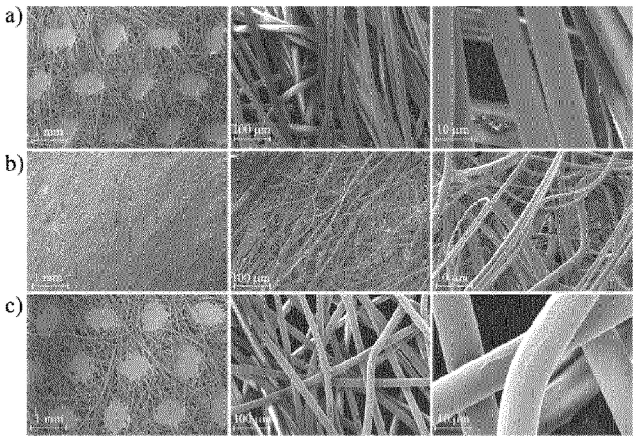

Fig. 5a

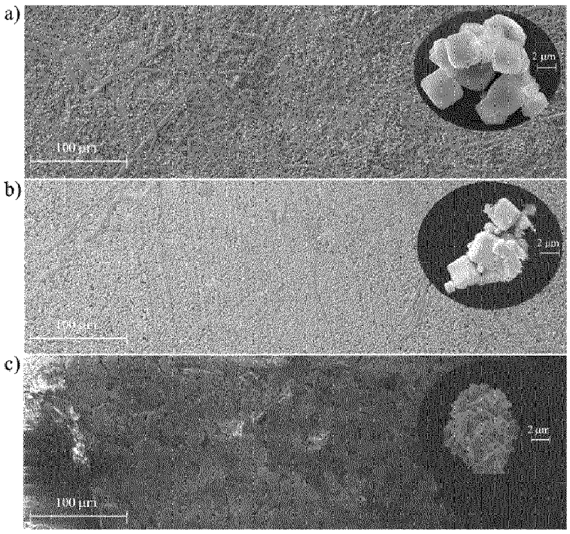

Fig. 5b

Fig. 5

Fig. 6 a)

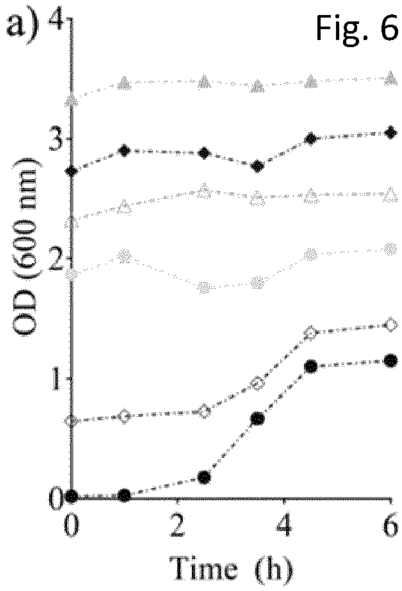

Fig. 6 b)

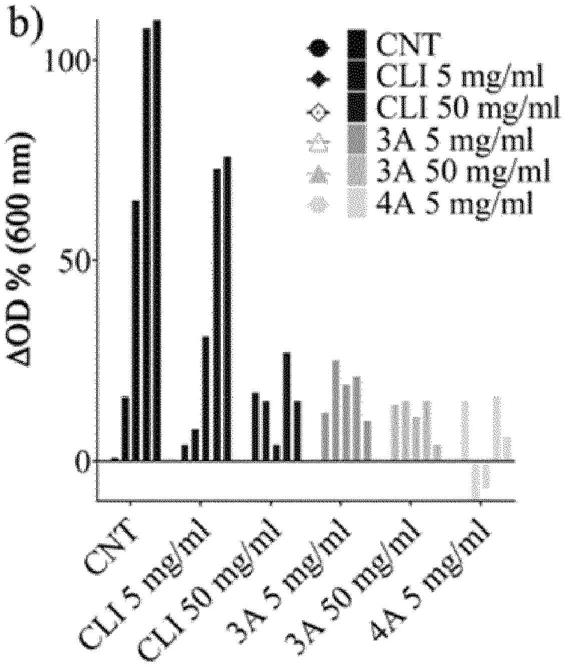

Fig. 6

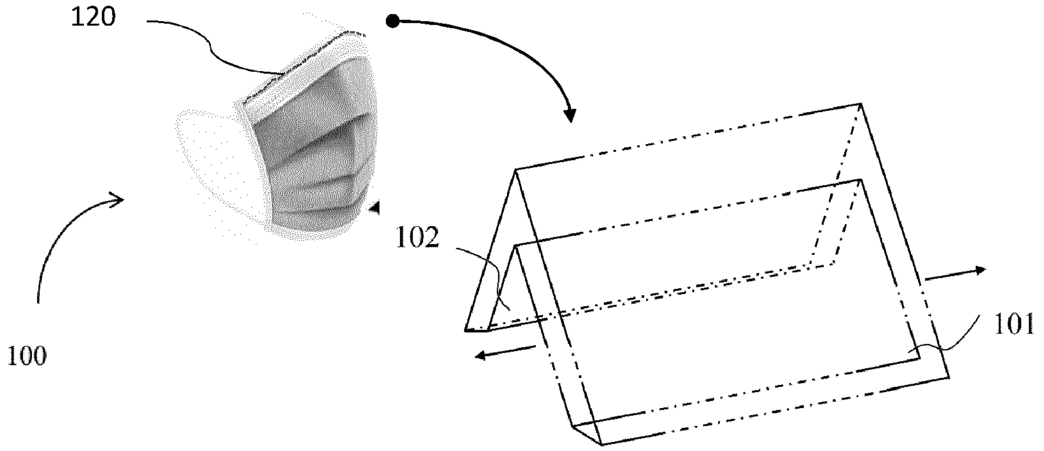

Fig. 7

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EUROPEAN SEARCH REPORT

Application Number
EP 21 17 4540

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1 The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	4 October 2021	Gkama, Alexandra

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X : particularly relevant if taken alone
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