Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2936110 A1 2015/07/30

(21) 2 936 110

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2014/12/19
(87) Date publication PCT/PCT Publication Date: 2015/07/30
(85) Entrée phase nationale/National Entry: 2016/07/06
(86) N° demande PCT/PCT Application No.: US 2014/071334
(87) N° publication PCT/PCT Publication No.: 2015/112292
(30) Priorité/Priority: 2014/01/24 (US61/931,158)

(51) Cl.Int./Int.Cl. *C12N 1/04* (2006.01), *A61L 15/36* (2006.01), *C12N 1/20* (2006.01)

(71) Demandeur/Applicant:
THE PROCTER & GAMBLE COMPANY, US

(72) Inventeurs/Inventors:
MCKIERNAN, ROBIN LYNN, US;
SONG, BRIAN ZIAOQING, US;
KEEGAN, SHARON ANNE, US

(74) Agent: TORYS LLP

(54) Titre : BANDE COMPRENANT UN ELEMENT FIBREUX CONTENANT DES MICRO-ORGANISMES ET SON PROCEDE DE FABRICATION

(54) Title: WEB COMPRISING A MICROORGANISM-CONTAINING FIBROUS ELEMENT AND METHOD FOR MAKING SAME

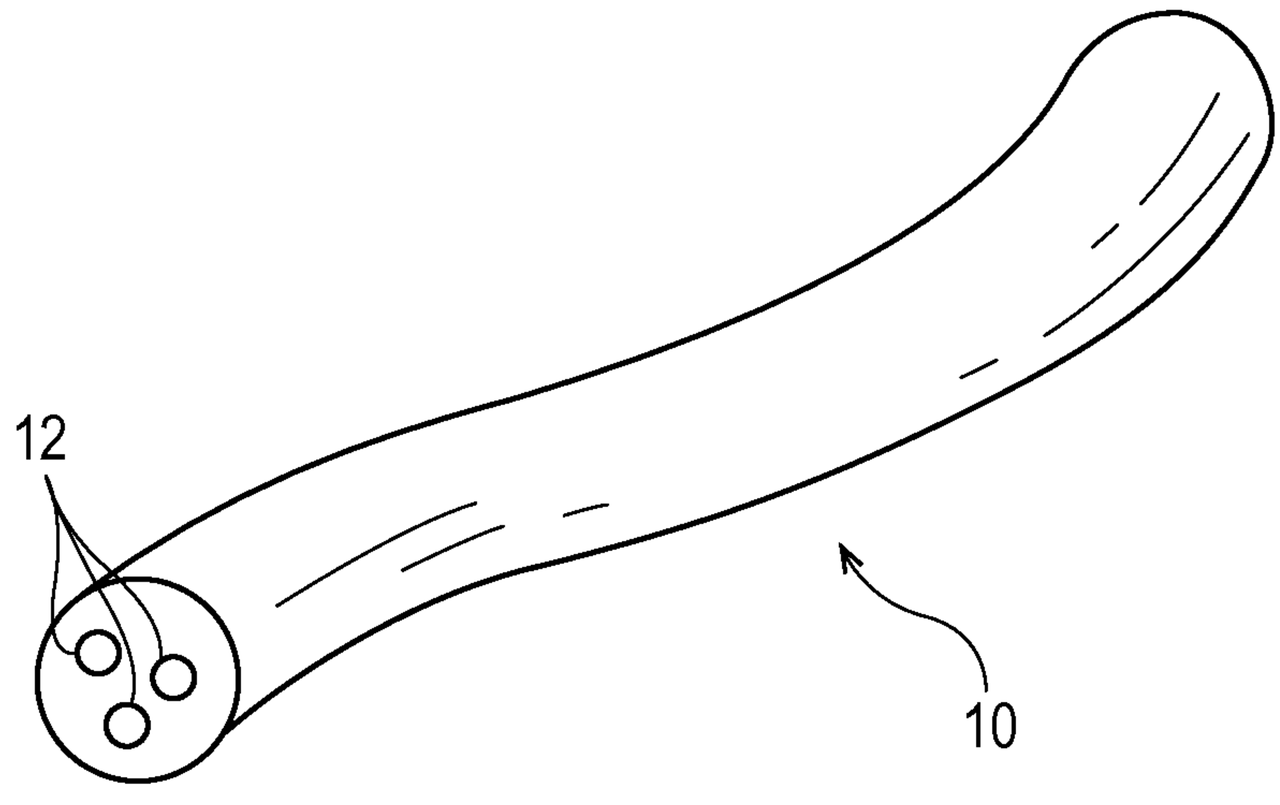

Fig. 1

(57) Abrégé/Abstract:
Webs containing one or more fibrous elements, such as filaments, wherein at least one of the fibrous elements contains one or more filament-forming materials and one or more microorganisms, for example a labile microorganism, and method for making same are provided.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 July 2015 (30.07.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/112292 A1

(51) International Patent Classification:
C12N 1/04 (2006.01) *A61L 15/36* (2006.01)
C12N 1/20 (2006.01)

(21) International Application Number:
PCT/US2014/071334

(22) International Filing Date:
19 December 2014 (19.12.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/931,158 24 January 2014 (24.01.2014) US

(71) Applicant: **THE PROCTER & GAMBLE COMPANY** [US/US]; One Procter & Gamble Plaza, Cincinnati, Ohio 45202 (US).

(72) Inventors: **MCKIERNAN, Robin, Lynn**; 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202 (US). **SONG, Brian, Ziaoqing**; 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202 (US). **KEEGAN, Sharon, Anne**; 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202 (US).

(74) Agent: **GUFFEY, Timothy B.**; The Procter & Gamble Company, Global Patent Services, One Procter & Gamble Plaza, C8-229, Cincinnati, Ohio 45202 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: WEB COMPRISING A MICROORGANISM-CONTAINING FIBROUS ELEMENT AND METHOD FOR MAKING SAME

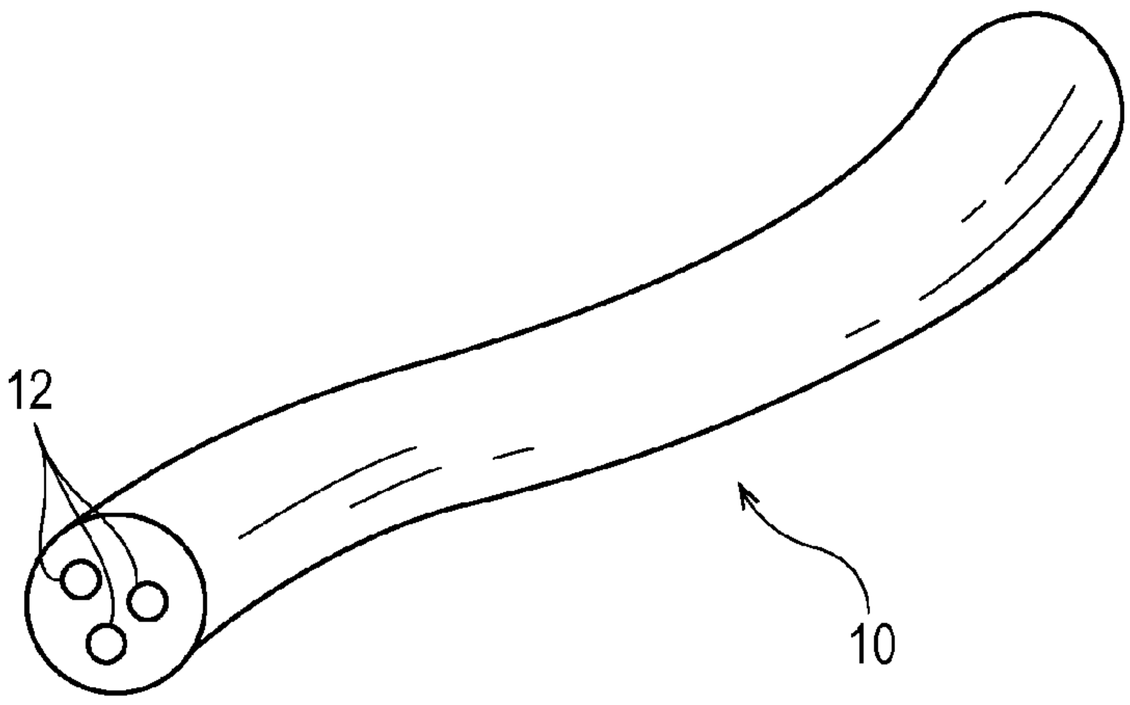

Fig. 1

(57) **Abstract**: Webs containing one or more fibrous elements, such as filaments, wherein at least one of the fibrous elements contains one or more filament-forming materials and one or more microorganisms, for example a labile microorganism, and method for making same are provided.

WO 2015/112292 A1

WEB COMPRISING A MICROORGANISM-CONTAINING FIBROUS ELEMENT AND METHOD FOR MAKING SAME

FIELD OF THE INVENTION

The present invention relates to a web comprising one or more fibrous elements, for example filaments, wherein at least one of the fibrous elements comprises one or more microorganisms, for example a labile microorganism, and more particularly to a web comprising filaments, for example meltblown and/or dry spun and/or spunbond rather than electrospun, and/or micron diameter (i.e., 1-100 micron diameter) rather than nano diameter filaments, comprising one or more filament-forming materials, such as a hydroxyl polymer, and one or more microorganisms, such as a probiotic, and method for making same.

BACKGROUND OF THE INVENTION

Electrospun and/or nanofiber filaments comprising biological active agents, such as bacteria and viruses are known. In one example, the electrospun and/or nanofiber filaments of the prior art are made from non-hydroxyl polymer filament-forming polymers, such as polyvinylpyrrolidone, which is not a hydroxyl polymer. In another example, the electrospun and/or nanofiber filaments of the prior art do not sufficiently stabilize their microorganisms during and/or after spinning of the filaments. For example, several microorganisms in one known electrospun filament had their viabilities significantly reduced by the electrospinning process and in order to prevent even loss of more viability the electrospun filaments had to be stored at temperatures of -20°C or below, which is not conducive for use by consumers of products made with such electrospun filaments.

Other known filaments comprising microorganisms fail to teach stabilizing the microorganisms within the filaments with or without stabilizing agents such that the microorganism exhibits less than a 2.5 log viability loss after being exposed to 25°C/60% relative humidity ("RH") conditions for 28 and/or 56 days as measured according to the Viability/Count Test Method described herein. Current distribution of products in commerce containing for example probiotics is done in special packaging which is moisture impermeable and maintains the probiotic containing material in a low humidity state so as to minimize the loss of microorganisms. Also, such products are kept at relatively low temperatures and in some instances are refrigerated or even frozen, which also is not conducive for use by consumers of such products.

Accordingly, one problem of known filaments comprising microorganisms is that the filaments fail to sufficiently stabilize the microorganisms such that the microorganisms exhibit less than a 5 (56 days) and/or 2.5 (28 days) log viability loss and/or contain at least 10^3 CFU/g of at least one of the microorganisms after being exposed to 25°C/60% RH conditions for 28 and/or 56 days as measured according to the Viability/Count Test Method described herein and/or release one or more microorganisms, such as the filament exhibits an average Disintegration Time of less than 1 hour as measured by the Dissolution Test Method described herein, and webs comprising such filaments are not known in the art.

One problem associated with delivering microorganisms, such as probiotics via a solid delivery vehicle, such as a web comprising a fibrous element, such as a filament, is that the probiotics lose their viability during and/or after formation of the solid delivery vehicle, such as a web comprising probiotic-containing filaments and/or don't release a sufficient amount, such as at least 10^3 CFU/g of at least one microorganism, especially in less than 1 hour (average Disintegration Time).

Accordingly, there is a need for a web comprising one or more fibrous elements, such as filaments, wherein at least one of the fibrous elements comprises one or more microorganisms, such as probiotics, that exhibit improved viability, for example as a result of improved stability, over known fibrous elements comprising microorganisms. There is also a need for a web comprising one or more fibrous elements, such as filaments, comprising at least 10^3 CFU/g of at least one microorganism. Further, there is a need for a web comprising one or more fibrous elements, such as filaments, comprising one or more microorganisms, wherein the web exhibits a Geometric Mean (GM) Tensile Strength, a GM Peak Elongation, and/or GM Modulus suitable for consumer's use of the web. Further yet, there is a need for a web comprising one or more fibrous elements, such as filaments, comprising one or more microorganisms, wherein the web exhibits an average Distintegration Time of less than 1 hour as measured according to the Dissolution Time Test Method described herein.

SUMMARY OF THE INVENTION

The present invention fulfills the need described above by providing a web comprising a fibrous element, such as a filament, such as a meltblown and/or dry spun and/or spunbond rather than electrospun, and/or micron diameter rather than nano diameter filament, comprising a microorganism that exhibits a viability and/or stability greater than known fibrous elements comprising microorganisms.

One solution to the problem identified above is a web comprising a fibrous element, such as a filament, comprising a filament-forming material and one or more microorganisms such that

at least one of the microorganisms present in the web and/or filament within the web exhibits less than a 5 (56 days) and/or a 2.5 (28 days) log viability loss and/or contains at least 10^3 CFU/g of at least one microorganism after being exposed to 25°C/60% RH conditions for 28 and/or 56 days as measured according to the Viability/Count Test Method and/or a web comprising one or more fibrous elements, such as filaments, comprising one or more microorganisms, wherein the web exhibits a Geometric Mean (GM) Tensile Strength, a GM Peak Elongation, and/or GM Modulus suitable for consumer's use of the web and/or a web comprising one or more fibrous elements, such as filaments, comprising one or more microorganisms, wherein the web exhibits an average Distintegration Time of less than 1 hour as measured according to the Dissolution Time Test Method described herein.

It has been unexpectedly found that filaments that contain one or more microorganisms of the present invention provide sufficient stability to the microorganisms to maintain their viability and/or count while present in the filament such that the microorganisms exhibit less than a 5 (56 days) and/or a 2.5 (28 days) log viability loss upon exposure to 25°C/60% RH conditions for 28 and/or 56 days and which can be released from the filament and/or web comprising the filament under conditions of intended use as evidenced by an average Disintegration Time of less than 1 hour as measured according to the Dissolution Test Method described herein.

In one example of the present invention, a web comprising a filament comprising a filament-forming material and one or more microorganisms, wherein at least one of the microorganisms exhibits less than a 2.5 log viability loss after being exposed to 25°C/60% RH conditions for 28 days as measured according to the Viability/Count Test Method described herein, is provided.

In another example of the present invention, a web comprising a filament comprising a filament-forming material and one or more microorganisms, wherein at least one of the microorganisms exhibits less than a 5 log viability loss after being exposed to 25°C/60% RH conditions for 56 days as measured according to the Viability/Count Test Method described herein, is provided.

In another example of the present invention, a web comprising a filament comprising one or more filament-forming materials, one or more microorganisms, and one or more stabilizing agents wherein the filament exhibits a cross-section that comprises two or more microorganisms, is provided.

In still another example of the present invention, a web comprising a filament comprising one or more filament-forming materials and one or more microorganisms, wherein the web and/or the filament within the web contains at least 10^3 CFU/g and/or at least 10^4 CFU/g and/or

at least 10^5 CFU/g and/or at least 10^6 CFU/g and/or at least 10^7 CFU/g and/or at least 10^8 CFU/g of at least one of the microorganisms after being exposed to 25°C/60% RH conditions for 28 and/or 56 days as measured according to the Viability/Count Test Method described herein, is provided.

In even another example of the present invention, a web comprising a filament comprising one or more filament-forming materials and one or more microorganisms wherein the web exhibits a GM Tensile Strength of greater than 200 g/in as measured according to the Tensile Test Method described herein, is provided.

In even another example of the present invention, a web comprising a filament comprising one or more filament-forming materials and one or more microorganisms wherein the web exhibits a GM Peak Elongation of greater than 5% and/or greater than 7% and/or greater than 10% as measured according to the Tensile Test Method described herein, is provided.

In even another example of the present invention, a web comprising a filament comprising one or more filament-forming materials and one or more microorganisms wherein the web exhibits a GM Modulus of less than 20,000 g/cm at 15 g/cm as measured according to the Tensile Test Method described herein, is provided.

In even still another example of the present invention, a web comprising a filament comprising one or more filament-forming materials and one or more microorganisms wherein the filament releases at least one microorganism and exhibits an average Disintegration Time of less than 1 hour as measured according to the Dissolution Test Method described herein, is provided.

In another example, a disposable absorbent article, for example a feminine hygiene pad, pantiliner, tampon, sanitary napkin, adult incontinence pad, adult incontinence pant, diaper, baby pant, toddler pant, overnight pant, swim pant, and mixtures thereof, comprising a web according to the present invention, is provided.

Accordingly, the present invention provides novel webs comprising fibrous elements, such as filaments, that comprise one or more microorganisms and a method for making same.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic representation of an example of a filament suitable for use in a web according to the present invention;

Fig. 2 is a schematic representation of an example of a process for making a filament according to the present invention;

Fig. 3 is a schematic representation of an example of a die suitable for use in the process of the present invention;

Fig. 4 is a front elevation view of a set-up for the Dissolution Test Method;

Fig. 5 is a partial top view of Fig. 4; and

Fig. 6 is a side elevation view of Fig. 4.

DETAILED DESCRIPTION OF THE INVENTION

Definitions

"Web" as used herein means a collection of fibrous elements, for example fibers and/or filaments, such as continuous filaments, of any nature or origin associated with one another. In one example, the web is a rectangular solid comprising fibrous elements that is formed via a spinning process, not a casting process.

In one example, a web according to the present invention means an orderly arrangement of filaments within a structure in order to perform a function. In one example, a web of the present invention is an arrangement comprising a plurality of two or more and/or three or more filaments that are inter-entangled. In one example, the web of the present invention may comprise, in addition to fibrous elements, one or more solid additives, such as particulates.

In one example, the web of the present invention comprises one or more fibrous elements, such as filaments, wherein at least one of the fibrous elements comprises one or more microorganisms.

In another example, the web of the present invention is water-soluble, for example the web comprises water-soluble fibrous elements comprising one or more microorganisms.

In yet another example, the web of the present invention may comprise one or more fibrous elements comprising one or more microorganisms and one or more fibrous elements void of microorganisms.

In still another example, the web of the present invention may comprise one or more water-soluble fibrous elements comprising one or more microorganisms and one or more water-insoluble fibrous elements.

In even another example, the web of the present invention may comprise one or more fibrous elements comprising one or more microorganisms and one or more solid additives, such as pulp fibers, for example wood pulp fibers.

"Fibrous element" as used herein means an elongate particulate having a length greatly exceeding its average diameter, i.e. a length to average diameter ratio of at least about 10. A fibrous element may be a filament or a fiber. In one example, the fibrous element is a single fibrous element rather than a yarn comprising a plurality of fibrous elements.

The fibrous elements of the present invention may be spun from a filament-forming compositions also referred to as fibrous element-forming compositions via suitable spinning process operations, such as meltblowing, spunbonding, electro-spinning, and/or rotary spinning.

The fibrous elements of the present invention may be monocomponent and/or multicomponent. For example, the fibrous elements may comprise bicomponent fibers and/or filaments. The bicomponent fibers and/or filaments may be in any form, such as side-by-side, core and sheath, islands-in-the-sea and the like.

"Filament" as used herein means an elongate particulate having a length greatly exceeding its diameter, i.e. a length to diameter ratio of at least about 10.

The filaments of the present invention may be spun from filament-forming compositions via suitable spinning process operations, such as meltblowing, dry spinning, and/or spunbonding.

The filaments of the present invention may be monocomponent and/or multicomponent. For example, the filaments may comprise bicomponent filaments. The bicomponent filaments may be in any form, such as side-by-side, core and sheath, islands-in-the-sea and the like.

The filaments of the present invention exhibit a length of greater than or equal to 5.08 cm (2 in.) and/or greater than or equal to 7.62 cm (3 in.) and/or greater than or equal to 10.16 cm (4 in.) and/or greater than or equal to 15.24 cm (6 in.).

Filaments are typically considered continuous or substantially continuous in nature. Filaments are relatively longer than fibers (which are less than 5.08 cm in length). Non-limiting examples of filaments include meltblown and/or spunbond filaments.

In one example, one or more fibers may be formed from a filament of the present invention, such as when the filaments are cut to shorter lengths (such as less than 5.08 cm in length). Thus, in one example, the present invention also includes a fiber made from a filament of the present invention, such as a fiber comprising one or more filament-forming materials and one or more microorganisms. Therefore, references to filament and/or filaments of the present invention herein also include fibers made from such filament and/or filaments unless otherwise noted. Fibers are typically considered discontinuous in nature relative to filaments, which are considered continuous in nature.

"Fiber" as used herein means an elongate particulate as described above that exhibits a length of less than 5.08 cm (2 in.) and/or less than 3.81 cm (1.5 in.) and/or less than 2.54 cm (1 in.).

Fibers are typically considered discontinuous in nature. Non-limiting examples of fibers include staple fibers produced by spinning a filament or filament tow of the present invention and

then cutting the filament or filament tow into segments of less than 5.08 cm (2 in.) thus producing fibers.

In one example, one or more fibers may be formed from a filament of the present invention, such as when the filaments are cut to shorter lengths (such as less than 5.08 cm in length). Thus, in one example, the present invention also includes a fiber made from a filament of the present invention, such as a fiber comprising one or more filament-forming materials and one or more additives, such as microorganisms. Therefore, references to filament and/or filaments of the present invention herein also include fibers made from such filament and/or filaments unless otherwise noted. Fibers are typically considered discontinuous in nature relative to filaments, which are considered continuous in nature.

"Filament-forming composition" as used herein means a composition that is suitable for making a filament of the present invention such as by meltblowing, dry spinning, and/or spunbonding. The filament-forming composition comprises one or more filament-forming materials that exhibit properties that make them suitable for spinning into a filament. In one example, the filament-forming material comprises a polymer. In addition to one or more filament-forming materials, the filament-forming composition may comprise one or more additives. In addition, the filament-forming composition may comprise one or more polar solvents, such as water, into which one or more, for example all, of the filament-forming materials and/or one or more, for example all, of the microorganisms and any additional additives, such as stabilizing agents and antioxidants, are dissolved and/or dispersed.

In one example as shown in Fig. 1 a filament 10 of the present invention made from a filament-forming composition of the present invention is such that one or more microorganisms 12, may be present in the filament rather than on the filament, such as a coating on an exterior surface of the filament, such as in the form of a coating. The total level of filament-forming materials and total level of microorganisms present in the filament-forming composition may be any suitable amount so long as the filaments of the present invention are produced therefrom. As is shown in Fig. 1, the cross-section of the filament may comprise two or more microorganisms.

In one example, one or more microorganisms may be present in the filament and one or more additional microorganisms may be present on a surface of the filament. In another example, a filament of the present invention may comprise one or more microorganisms that are present in the filament when originally made, but then are liberated from the filament when exposed to conditions of intended use of the filament.

"Filament-forming material" as used herein means a material, such as a polymer or monomers capable of producing a polymer that exhibits properties suitable for making a

filament. In one example, the filament-forming material comprises one or more substituted polymers such as an anionic, cationic, zwitterionic, and/or nonionic polymer. In another example, the polymer may comprise a hydroxyl polymer, such as a polyvinyl alcohol ("PVOH") and/or a polysaccharide, such as starch and/or a starch derivative, such as an ethoxylated starch and/or acid-thinned starch. In yet another example, the filament-forming material is a polar solvent-soluble material.

"Stabilizing agent" as used herein means a material that improves the viability of the microorganism, for example by preventing and/or mitigating the dehydration of the microorganisms during and/or after the formation of the filament containing the microorganism.

"Additive" as used herein means any material present in the filament of the present invention that is not a filament-forming material or a microorganism. In one example, an additive comprises a processing aid. In still another example, an additive comprises a filler. In one example, an additive comprises any material present in the filament that its absence from the filament would not result in the filament losing its filament structure, in other words, its absence does not result in the filament losing its solid form.

In one example, an additive comprises a stabilizing agent, for example a carbohydrate and/or protein, which provides the microorganism a stabilized environment within the filament.

In another example, an additive comprises an antioxidant.

In another example, an additive comprises a plasticizer for the filament. The filaments of the present invention may comprise one or more plasticizers. When present, the plasticizers may be present in the filament at a level of from about 0.01% to about 5% and/or from about 0.05% to about 3% and/or from about 0.05% to about 1% and/or from about 0.1 to about 0.5% by weight on a dry filament basis.

Non-limiting examples of suitable plasticizers for the present invention include polyols, copolyols, polycarboxylic acids, polyesters and dimethicone copolyols. Examples of useful polyols include, but are not limited to, glycerin, diglycerin, propylene glycol, ethylene glycol, butylene glycol, pentylene glycol, cyclohexane dimethanol, hexanediol, 2,2,4-trimethylpentane-1,3-diol, polyethylene glycol (200-600), pentaerythritol, sugar alcohols such as sorbitol, manitol, lactitol and other mono- and polyhydric low molecular weight alcohols (e.g., C2-C8 alcohols).

In one example, the plasticizer includes glycerin and/or propylene glycol and/or glycerol derivatives such as propoxylated glycerol. In still another example, the plasticizer is selected from the group consisting of glycerin, ethylene glycol, polyethylene glycol, propylene glycol, glycidol, urea, sorbitol, xylitol, maltitol, ethylene bisformamide, and mixtures thereof

In another example, an additive comprises a crosslinking agent suitable for crosslinking one or more of the filament-forming materials present in the filaments of the present invention. In one example, the crosslinking agent comprises a crosslinking agent capable of crosslinking hydroxyl polymers together, for example via their hydroxyl moieties. Non-limiting examples of suitable crosslinking agents include imidazolidinones, polycarboxylic acids and mixtures thereof. In one example, the crosslinking agent comprises a urea glyoxal adduct crosslinking agent, for example a dihydroxyimidazolidinone, such as dihydroxyethylene urea ("DHEU"). A crosslinking agent can be present in the filament-forming composition and/or filament of the present invention to control the filament's solubility and/or dissolution in a solvent, such as a polar solvent. Use of crosslinking agents provides a means for regulating the dissolution performance of filaments of the present invention.

In another example, an additive comprises a modifier, such as a shear modifier and/or an extensional modifier. Non-limiting examples of rheology modifiers include but are not limited to polyacrylamide, polyethylene oxides, polyurethanes and polyacrylates that may be used in the filaments of the present invention. Non-limiting examples of rheology modifiers are commercially available from The Dow Chemical Company (Midland, MI).

In yet another example, an additive comprises one or more colors and/or dyes that are incorporated into the filaments of the present invention to provide a visual signal when the filaments are exposed to conditions of intended use and/or when a microorganism is released from the filaments and/or when a filament's morphology changes.

In yet another example, an additive comprises one of more sensorial agents that are incorporated into the filaments of the present invention to provide cooling, warming or other sensorial signals during use. Non-limiting examples of sensorial agents include cooling sensates and/or warming sensates, perfumes, odor control agents, and mixtures thereof.

In still yet another example, an additive comprises one or more release agents and/or lubricants. Non-limiting examples of suitable release agents and/or lubricants include fatty acids, fatty acid salts, fatty alcohols, fatty esters, sulfonated fatty acid esters, fatty amine acetates, fatty amide, silicones, aminosilicones, fluoropolymers, and mixtures thereof. In one example, the release agents and/or lubricants are applied to the filament, in other words, after the filament is formed. In one example, one or more release agents/lubricants are applied to the filament prior to collecting the filaments on a collection device to form a web. In another example, one or more release agents/lubricants are applied to a web formed from the filaments of the present invention prior to contacting one or more webs, such as in a stack of webs. In yet another example, one or more release agents/lubricants are applied to the filament of the present invention and/or web

comprising the filament prior to the filament and/or web contacting a surface, such as a surface of equipment used in a processing system so as to facilitate removal of the filament and/or web and/or to avoid layers of filaments and/or webs of the present invention sticking to one another, even inadvertently. In one example, the release agents/lubricants comprise particulates.

In even still yet another example, an additive comprises one or more anti-blocking and/or detackifying agents. Non-limiting examples of suitable anti-blocking and/or detackifying agents include starches, starch derivatives, crosslinked polyvinylpyrrolidone, crosslinked cellulose, microcrystalline cellulose, silica, metallic oxides, calcium carbonate, talc, mica, and mixtures thereof.

In one example, an additive comprises a pH buffering agent, for example sodium citrate dehydrate.

"Conditions of intended use" as used herein means the temperature, moisture, such as water, bodily fluids, such as saliva and/or menstrual fluids, pH, and/or mechanical conditions that a web comprising a fibrous element, such as a filament, of the present invention is exposed to when the web is used for one or more of its designed purposes. For example, if a filament is designed to be used in a feminine hygiene product, the conditions of intended use will include those temperature, moisture, urine, sweat, menstrual or other bodily fluids, pH, and/or mechanical, such as friction, conditions present during use of the feminine hygiene product. In another example, if a filament is designed to be used in an oral care product, the conditions of intended use will include those temperature, moisture, saliva, pH, and/or mechanical conditions present during use of the oral care product by a human or in an animal. Likewise, if a filament is designed to be used in a household cleaning product, the conditions of intended use will include the temperature, moisture, such as resulting from wetting the filament with water, and/or mechanical conditions present during use of the household cleaning product. In addition to the above, the filaments of the present invention may be used in food for humans and/or pets.

"Treats" as used herein with respect to treating a surface or environment means that one or more of the microorganisms provide a benefit to a surface or environment. Treats includes regulating and/or immediately improving a surface's or environment's appearance, cleanliness, smell, purity and/or feel. In one example treating in reference to treating a keratinous tissue (for example skin and/or hair) surface means regulating and/or immediately improving the keratinous tissue's cosmetic appearance and/or feel. For instance, "regulating skin, hair, or nail (keratinous tissue) condition" includes: thickening of skin, hair, or nails (e.g, building the epidermis and/or dermis and/or sub-dermal [e.g., subcutaneous fat or muscle] layers of the skin, and where applicable the keratinous layers of the nail and hair shaft) to reduce skin, hair, or nail atrophy,

increasing the convolution of the dermal-epidermal border (also known as the rete ridges), preventing loss of skin or hair elasticity (loss, damage and/or inactivation of functional skin elastin) such as elastosis, sagging, loss of skin or hair recoil from deformation; melanin or non-melanin change in coloration to the skin, hair, or nails such as under eye circles, blotching (e.g., uneven red coloration due to, e.g., rosacea) (hereinafter referred to as "red blotchiness"), sallowness (pale color), discoloration caused by telangiectasia or spider vessels, and graying hair.

In one example, one or more of the microorganisms may perform its function (i.e., treat) upon ingestion and/or consuming by an animal, for example a mammal, such as a human, by way of mouth, nose, eyes, ears, skin pores, rectum, vagina, or other orifice or wound (such as delivering a microorganism by wound dressing) in the animal. Non-limiting examples of products comprising webs comprising fibrous elements, such as filaments, of the present invention that are intended for ingestion include feminine hygiene products (for example tampons, pads, panty liners), baby care products, oral care products such as teeth whitening products, gum health products, floss, medicinal products, dietary products (for example delivered in a new food form), personal health care, beauty care and pet care products, and mixtures thereof.

"Weight ratio" as used herein means the weight of filament-forming material (g or %) on a dry weight basis in the filament to the weight of additive, such as microorganism(s) (g or %) on a dry weight basis in the filament.

"Hydroxyl polymer" as used herein includes any hydroxyl-containing polymer that can be incorporated into a filament of the present invention, for example as a filament-forming material. In one example, the hydroxyl polymer of the present invention includes greater than 20% and/or greater than 50% and/or greater than 90% by weight hydroxyl moieties.

"Non-cellulose-containing" as used herein with respect to the filaments of the present invention means that less than 5% and/or less than 3% and/or less than 1% and/or less than 0.1% and/or 0% by weight of cellulose polymer, cellulose derivative polymer and/or cellulose copolymer is present in filament. In one example, "non-cellulose-containing" means that less than 5% and/or less than 3% and/or less than 1% and/or less than 0.1% and/or 0% by weight of cellulose polymer is present in filament.

"Polar solvent-soluble material" as used herein with respect to the filaments of the present invention means a material that is miscible in a polar solvent. In one example, a polar solvent-soluble material is miscible in alcohol and/or water. In other words, a polar solvent-soluble material is a material that is capable of forming a stable (does not phase separate for greater than

5 minutes after forming the homogeneous solution) homogeneous solution with a polar solvent, such as alcohol and/or water at ambient conditions.

"Alcohol-soluble material" as used herein with respect to the filaments of the present invention means a material that is miscible in alcohol. In other words, a material that is capable of forming a stable (does not phase separate for greater than 5 minutes after forming the homogeneous solution) homogeneous solution with an alcohol at ambient conditions.

"Water-soluble material" as used herein with respect to the filaments of the present invention means a material that is miscible in water. In other words, a material that is capable of forming a stable (does not separate for greater than 5 minutes after forming the homogeneous solution) homogeneous solution with water at ambient conditions.

"Ambient conditions" as used herein means 23°C ± 2.2°C and a relative humidity of 50% ± 10%.

"Length" as used herein, with respect to a filament, means the length along the longest axis of the filament from one terminus to the other terminus. If a filament has a kink, curl or curves in it, then the length is the length along the entire path of the filament.

"Diameter" as used herein, with respect to a filament, is measured according to the Diameter Test Method described herein. In one example, a filament of the present invention exhibits a diameter of less than 100 μm and/or less than 75 μm and/or less than 50 μm and/or less than 25μm and/or less than 20 μm and/or less than 15 μm and/or less than 10 μm and/or greater than 1 μm and/or greater than 3 μm and/or greater than 5 μm and/or greater than 7 μm.

"Triggering condition" as used herein in one example means anything, such as an act or event, that serves as a stimulus and initiates a change in the filament, such as a loss or altering of the filament's physical structure, swelling, gelling or dissolution of the filament and/or a release of a microorganism from the filament. In another example, the triggering condition may be present in an environment, such as water, when a filament of the present invention is added to the water. In other words, nothing changes in the water except for the fact that the filament of the present invention is added to the water.

"Morphology changes" as used herein with respect to a filament's morphology changing means that the filament experiences a change in its physical structure. Non-limiting examples of morphology changes for a filament of the present invention include dissolution, melting, swelling, shrinking, breaking into pieces, exploding, lengthening, shortening, and combinations thereof. The filaments of the present invention may completely or substantially lose their filament physical structure or they may have their morphology changed or they may retain or

substantially retain their filament physical structure as they are exposed to conditions of intended use.

"By weight on a dry web and/or filament basis" means the weight of the web and/or filament measured immediately after the web and/or filament has been placed in a dessicator with a dessicant, for example a dessicator/dessicant commercially available from Desican Inc. under the tradename M-3003-66 which uses a molecular sieve dessicant, for at least 24 hours. The weight of the web and/or filament is measured in a conditioned room at a temperature of 23°C ± 2.2°C and a relative humidity of 50% ± 10% immediately after removing the web and/or filament from the dessicator/dessicant. In one example, "by weight on a dry web and/or filament basis" means that the web and/or filament may comprise less than 20% and/or less than 15% and/or less than 10% and/or less than 7% and/or less than 5% and/or less than 3%, but greater than 0% by weight on a dry web and/or filament basis of moisture, such as water, for example free water.

"Total level" as used herein, for example with respect to the total level of one or more additives, for example microorganisms, present in the web and/or filament within the web, means the sum of the weights, the sum of the colony forming units/g of web and/or filament ("CFU/g") of microorganisms, or weight percent of all of the other (non-microorganism) additives. In other words, a web and/or filament within the web may comprise at least 10^3 CFU/g and/or at least 10^4 CFU/g and/or at least 10^5 CFU/g and/or at least 10^6 CFU/g and/or at least 10^7 CFU/g and/or at least 10^8 CFU/g by weight on a dry web and/or filament basis, of one or more microorganisms. In another example, a web and/or filament of the present invention may comprise one or more non-microorganism additives in the web and/or filament at a total level of at least 1% and/or at least 5% and/or at least 10% and/or at least 20% and/or up to 50% by weight on a dry web and/or filament basis.

"Labile microorganism" as used herein means a microorganism that is likely to undergo change, for example a microorganism that is likely to lose all or a substantial part (at least a 1 log viability loss or greater as measured according to the Viability/Count Test Method described herein) when exposed to stresses, for example humidity, temperature, shear, aerobic conditions. A non-limiting example of a stress is exposing the microorganism to 25°C/60% RH conditions for 28 and/or 56 days. The *L. fermentum* in the Example below is an example of a labile microorganism as used herein.

As used herein, the articles "a" and "an" when used herein, for example, "an anionic surfactant" or "a fiber" is understood to mean one or more of the material that is claimed or described.

All percentages and ratios are calculated by weight unless otherwise indicated. All percentages and ratios are calculated based on the total composition unless otherwise indicated.

Unless otherwise noted, all component or composition levels are in reference to the active level of that component or composition, and are exclusive of impurities, for example, residual solvents or by-products, which may be present in commercially available sources.

Web

The web of the present invention comprises one or more fibrous elements, for example one or more filaments, comprising one or more microorganisms.

The web of the present invention may comprise a water activity of less than 0.2 and/or from 0 to about 0.2 and/or from greater than 0 to less than 0.15 as measured according to the Water Activity Test Method described herein.

In one example, a web of the present invention may exhibit an average Disintegration Time of less than 1 hour and/or less than 30 minutes and/or less than 10 minutes and/or less than 5 minutes and/or less than 1 minute and/or less than 30 seconds and/or less than 10 seconds and/or less than 5 seconds and/or may be instantaneous as measured according to the Dissolution Test Method described herein.

In one example, a web of the present invention may exhibit an average Dissolution Time of less than 12 hours and/or less than 6 hours and/or less than 1 hour and/or less than 30 minutes and/or less than 10 minutes and/or less than 5 minutes and/or less than 1 minute and/or less than 30 seconds and/or less than 10 seconds and/or less than 5 seconds and/or may be instantaneous as measured according to the Dissolution Test Method described herein.

In another example, the web of the present invention exhibits an average Disintegration Time per gsm of web of about 10 seconds/gsm (s/gsm) or less, and/or about 5 s/gsm or less, and/or about 3 s/gsm or less, and/or about 2 s/gsm or less, and/or about 1 s/gsm or less, and/or about 0.5 s/gsm or less as measured according to the Dissolution Test Method described herein.

In another example, the web of the present invention exhibits an average Dissolution Time per gsm of web of about 10 seconds/gsm (s/gsm) or less, and/or about 5 s/gsm or less, and/or about 3 s/gsm or less, and/or about 2 s/gsm or less, and/or about 1.8 s/gsm or less, and/or about 1.5 s/gsm or less as measured according to the Dissolution Test Method described herein.

In one example of the present invention, a web comprising one or more microorganisms, wherein the web material exhibits a basis weight of less than 5000 g/m^2 and/or less than 4000 g/m^2 and/or less than 2000 g/m^2 and/or less than 1000 g/m^2 and/or less than 500 g/m^2 and/or less

than 300 g/m^2 and/or less than 200 g/m^2 as measured by the Basis Weight Test Method described herein is provided.

In another example of the present invention, a web comprising one or more microorganisms, wherein the web material exhibits a thickness of greater than 0.01 mm and/or greater than 0.05 mm and/or greater than 0.1 mm and/or to about 20 mm and/or to about 10 mm and/or to about 5 mm and/or to about 2 mm and/or to about 0.5 mm and/or to about 0.3 mm as measured by the Thickness Test Method described herein is provided herein.

In another example of the present invention a web comprising one or more microorganisms, wherein the web material exhibits a GM Tensile Strength of greater than 200 g/in and/or greater than 400 g/in and/or greater than 500 g/in and/or greater than 750 g/in as measured according to the Tensile Test Method described herein is provided.

In still yet another example of the present invention, a web comprising one or more microorganisms, wherein the web material exhibits a Geometric Mean (GM) Peak Elongation of greater than 5% and/or greater than 10% and/or greater than 20% and/or greater than 30% and/or greater than 50% and/or to about 200% and/or to about 100% and/or to about 75% as measured according to the Tensile Test Method described herein is provided.

In still another example of the present invention, a web material comprising one or more microorganisms, wherein the web material exhibits a Geometric Mean (GM) Modulus of less than 20,000 g/cm at 15 g/cm and/or less than 15,000 g/cm at 15 g/cm and/or less than 12,000 g/cm at 15 g/cm and/or less than 10,000 g/cm at 15 g/cm and/or less than 8,000 g/cm at 15 g/cm and/or greater than 10 g/cm at 15 g/cm and/or greater than 50 g/cm at 15 g/cm and/or greater than 100 g/cm at 15 g/cm and/or greater than 500 g/cm at 15 g/cm and/or greater than 1,000 g/cm at 15 g/cm as measured by the Tensile Test Method described herein is provided.

In even yet another example of the present invention, a web comprising one or more microorganisms, wherein the web material exhibits a Density of less than 0.50 g/cm^3 and/or less than 40 g/cm^3 and/or less than 0.38 g/cm^3 and/or less than 0.25g/cm^3 and/or less than 0.10 g/cm^3 as measured according to the Density Test Method described herein is provided.

In yet another example of the present invention, a web comprising one or more microorganisms, wherein the web material exhibits a Plate Stiffness of less than 50 N*mm and/or less than 40 N*mm and/or less than 30 N*mm and/or less than 20 N*mm and/or less than 15 N*mm and/or less than 10 N*mm and/or less than 7 N*mm and/or less than 5 N*mm and/or less than 3 N*mm as measured according to the Plate Stiffness Test Method described herein is provided.

In one example, a first web of the present invention may be combined with a second web to form a multi-ply, for example 2-ply, product. In one example, the second web may comprise fibrous elements comprising zero or one or more microorganisms different from the microorganisms present in the fibrous elements of the first web. In another example, the second web may comprise fibrous elements that exhibit different properties, such as being water-insoluble, than the fibrous elements of the first web. In still another example, the second web may comprise fibrous elements comprising different filament-forming materials, such as thermoplastic polymers, for example polypropylene, polyethylene, and/or polyester, that are different from the filament-forming materials present in the fibrous elements of the first web.

The webs of the present invention may be designed for use in various applications such as for use in feminine hygiene products, for example pads, tampons, pantiliners, oral care products, for example floss and/or teeth strips, home care products, for example floor cleaning pads.

Fibrous Elements

The fibrous elements of the present invention may comprise one or more microorganisms. The fibrous elements may comprise filaments comprising one or more microorganisms. The fibrous elements may comprise fibers, which may be formed by spinning filaments and then cutting the filaments into fibers, comprising one or more microorganisms.

The following discussion is directed to filaments, but with the understanding that such filaments may be cut into fibers and used to make webs of the present invention.

Filament

The filaments of the present invention comprise a filament-forming material and one or more microorganisms. In one example, the one or more microorganisms are present within the filament rather than being present only as a surface coating or partially embedded on the filaments.

In one example, at least one of the microorganisms present in a filament of the present invention exhibits less than a 2.5 log and/or less than a 2.25 and/or less than a 2 log and/or less than a 1.5 and/or less than a 1 log viability loss after being exposed to 25°C/60% RH conditions for 28 days as measured according to the Viability/Count Test Method described herein.

In one example, at least one of the microorganisms present in a filament of the present invention exhibits less than a 5 log and/or less than a 4.5 log and/or less than a 4 log and/or less than a 3.5 log and/or less than a 3 log and/or less than a 2.5 log and/or less than a 2.25and/or less than a 2 log and/or less than a 1.5 and/or less than a 1 log viability loss after being exposed to

25°C/60% RH conditions for 56 days as measured according to the Viability/Count Test Method described herein.

In one example, at least one of the microorganisms present in the filament of the present invention is releasable from the filament when exposed to conditions of intended use.

In one example, the total level of filament-forming materials present in a filament of the present invention is less than 90% and/or less than 80% and/or less than 70% and/or less than 60% by weight on a dry filament basis and the total level of the one or more microorganisms present in the filament is less than 50% and/or greater than 1% by weight on a dry filament basis.

In addition to the filament-forming materials and the microorganisms, the filaments of the present invention may comprise one or more stabilizing agents. In one example, the total level of stabilizing agents present in the filament of the present invention is less than 60% and/or greater than 10% by weight on a dry filament basis.

In another example, the filament may further comprise an antioxidant. The total level of antioxidants present in a filament of the present invention is less than 1% and/or to 0% by weight on a dry filament basis.

In still another example, the filament of the present invention comprises from about 20% and/or from about 30% and/or from about 40% to about 50% and/or to about 60% and/or to about 70% by weight on a dry filament basis of a filament-forming material, such as polyvinyl alcohol polymer and/or a starch polymer, and at least 10^3 CFU/g and/or at least 10^4 CFU/g and/or at least 10^5 CFU/g and/or at least 10^6 CFU/g and/or at least 10^7 CFU/g and/or at least 10^8 CFU/g by weight on a dry filament of one or more microorganisms.

In one example, the filaments of the present invention may be meltblown filaments. In another example, the filaments of the present invention may be spunbond filaments. In another example, the filaments may be hollow filaments prior to and/or after release of one or more of its microorgansims.

The filaments of the present invention may be hydrophilic or hydrophobic. The filaments may be surface treated and/or internally treated to change the inherent hydrophilic or hydrophobic properties of the filament.

In one example, the filament exhibits an average diameter of less than 100 μm and/or less than 75 μm and/or less than 50 μm and/or less than 25μm and/or less than 20 μm and/or less than 15 μm and/or less than 10 μm and/or greater than 1 μm and/or greater than 3 μm and/or greater than 5 μm and/or greater than 7 μm as measured according to the Diameter Test Method described herein. In another example, the filament of the present invention exhibits a diameter of greater than 1 μm as measured according to the Diameter Test Method described herein. The

diameter of a filament of the present invention may be used to control the rate of release of one or more microorganisms present in the filament and/or the rate of loss and/or altering of the filament's physical structure.

The filament present in the web of the present invention may comprise two or more different microorganisms. In one example, the filament comprises two or more different microorganisms, wherein the two or more different microorganisms are compatible with one another. In another example, the filament comprises two or more different microorganisms, wherein the two or more different microorganisms are incompatible with one another.

In one example, the filament may comprise a microorganism within the filament and a microorganism on an external surface of the filament, such as a surface coating or partially embedded in the filament. The microorganism on the external surface of the filament may be the same or different from the microorganism present in the filament. If different, the microorganisms may be compatible or incompatible with one another.

In one example, one or more microorganisms may be uniformly distributed or substantially uniformly distributed throughout the filament. In another example, one or more microorganisms may be distributed as discrete regions within the filament such that one portion of the filament contains microorganisms and another portion of the filament is void of microorganisms. In still another example, at least one microorganism is distributed uniformly or substantially uniformly throughout the filament and at least another microorganism is distributed as one or more discrete regions within the filament. In still yet another example, at least one microorganism is distributed as one or more discrete regions within the filament and at least another microorganism is distributed as one or more discrete regions different from the first discrete regions within the filament. In even another example, the filament of the present invention may contain one or more microorganisms such that a cross-section of the filament comprises at least two microorganisms. Still yet another example of the filament of the present invention is a bicomponent filament wherein the core contains microorganisms and the sheath is void of microorganisms or the core is void of microorganisms and the sheath contains microorganisms or the core contains a first microorganism and the sheath contains a second micoorgansim different from the first microorganism or the core contains one or more microorganisms and the sheath contains one or more filament-forming materials. In another example of a bicomponents filament, such as a side-by-side bicomponent filament, one side may contain a microorganism and the other side may be void of microorganisms or one side may contain a first microorganism and the other side may contain a second microorganism different from the first microorganism.

The filaments may be used as discrete articles. In one example, the filaments may be applied to and/or deposited on a carrier substrate, such as a disposable absorbent article, for example a wipe, paper towel, bath tissue, facial tissue, sanitary napkin, tampon, feminine hygiene pad, pantiliner, diaper, baby pant, toddler pant, overnight pant, swim pant, adult incontinence article such as an adult incontinence pad and/or an adult incontinence pant, washcloth, dryer sheet, laundry sheet, laundry bar, dry cleaning sheet, netting, filter paper, fabrics, clothes, undergarments, and the like.

In one example, the filaments of the present invention are water-soluble.

In another example, the filaments of the present invention edible, ingestible, and/or consumable by humans and/or animals. In other words, the filaments of the present invention are made from suitable materials, for example filament-forming materials and microorganisms, that are safe for human and/or animal ingestion and/or consumption such that the webs made from such filaments are safe for human and/or animal ingestion and/or consumption.

Filament-forming Materials

The filaments of the present invention comprise one or more filament-forming materials. The filament-forming materials may be present in the filament at a total level of from about 10% to about 90% and/or from about 20% to about 80% and/or from about 30% to about 70% and/or from about 40% to about 60% by weight on a dry filament basis.

In one example, the filament-forming material may comprise a polar solvent-soluble material, such as an alcohol-soluble material and/or a water-soluble material. Non-limiting examples of polar solvent-soluble materials include polar solvent-soluble polymers. The polar solvent-soluble polymers may be synthetic or natural original and may be chemically and/or physically modified. In one example, the polar solvent-soluble polymers exhibit a weight average molecular weight of at least 10,000 g/mol and/or at least 20,000 g/mol and/or at least 40,000 g/mol and/or at least 80,000 g/mol and/or at least 100,000 g/mol and/or at least 1,000,000 g/mol and/or at least 3,000,000 g/mol and/or at least 10,000,000 g/mol and/or at least 20,000,000 g/mol and/or to about 40,000,000 g/mol and/or to about 30,000,000 g/mol.

In one example, the water-soluble hydroxyl polymer is selected from the group consisting of: polyvinyl alcohols, hydroxymethylcelluloses, hydroxyethylcelluloses, hydroxypropylmethylcelluloses and mixtures thereof. A non-limiting example of a suitable polyvinyl alcohol includes those commercially available from Sekisui Specialty Chemicals America, LLC (Dallas, TX) under the CELVOL® trade name. A non-limiting example of a suitable hydroxypropylmethylcellulose includes those commercially available from the Dow

Chemical Company (Midland, MI) under the METHOCEL® trade name including combinations with above mentioned hydroxypropylmethylcelluloses.

In one example the polyvinyl alcohols herein can be grafted with other monomers to modify its properties. A wide range of monomers has been successfully grafted to polyvinyl alcohol. Non-limiting examples of such monomers include vinyl acetate, styrene, acrylamide, acrylic acid, 2-hydroxyethyl methacrylate, acrylonitrile, 1,3-butadiene, methyl methacrylate, methacrylic acid, maleic acid, itaconic acid, sodium vinylsulfonate, sodium allylsulfonate, sodium methylallyl sulfonate, sodium phenylallylether sulfonate, sodium phenylmethallylether sulfonate, 2-acrylamido-methyl propane sulfonic acid (AMPs), vinylidene chloride, vinyl chloride, vinyl amine and a variety of acrylate esters.

In yet another example, the filament-forming material may be a film-forming material. In still yet another example, the filament-forming material may be synthetic or of natural origin and it may be chemically, enzymatically, and/or physically modified.

In even another example of the present invention, the filament-forming material may comprise a polymer selected from the group consisting of: polymers derived from acrylic monomers such as the ethylenically unsaturated carboxylic monomers and ethylenically unsaturated monomers, polyvinyl alcohol, polyacrylates, polymethacrylates, copolymers of acrylic acid and methyl acrylate, polyvinylpyrrolidones, polyalkylene oxides, starch and starch derivatives, pullulan, gelatin, hydroxypropylmethylcelluloses, methycelluloses, and carboxymethycelluloses.

In still another example, the filament-forming material may comprises a polymer selected from the group consisting of: polyvinyl alcohol, polyvinyl alcohol derivatives, starch, starch derivatives, cellulose derivatives, hemicellulose, hemicellulose derivatives, proteins, sodium alginate, hydroxypropyl methylcellulose, chitosan, chitosan derivatives, polyethylene glycol, polyethylene oxide, polyacrylamide, tetramethylene ether glycol, polyvinyl pyrrolidone, hydroxymethyl cellulose, hydroxyethyl cellulose, and mixtures thereof.

In another example, the filament-forming material comprises a polymer is selected from the group consisting of: pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, sodium alginate, xanthan gum, tragacanth gum, guar gum, acacia gum, Arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, dextrin, pectin, chitin, levan, elsinan, collagen, gelatin, zein, gluten, soy protein, casein, polyvinyl alcohol, starch, starch derivatives, hemicellulose, hemicellulose derivatives, proteins, chitosan, chitosan derivatives, polyethylene glycol, tetramethylene ether glycol, hydroxymethyl cellulose, and mixtures thereof.

In another example, the filament-forming material is selected from the group consisting of: polyvinyl alcohol, polyvinyl alcohol derivatives, polyethylene oxide, starch, starch derivatives, cellulose, cellulose derivatives, carboxymethyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, sodium alginate, xanthan gum, tragacanth gum, guar gum, acacia gum, Arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, chitosan, chitosan derivatives, polyethylene glycol, hemicellulose, hemicelluloses derivatives, polyacrylamide, and copolymers and mixtures thereof.

In one example, the polar solvent-soluble polymers are selected from the group consisting of: alcohol-soluble polymers, water-soluble polymers and mixtures thereof. Non-limiting examples of water-soluble polymers include water-soluble hydroxyl polymers, water-soluble thermoplastic polymers, water-soluble biodegradable polymers, water-soluble non-biodegradable polymers and mixtures thereof. In one example, the water-soluble polymer comprises polyvinyl alcohol. In another example, the water-soluble polymer comprises carboxymethylcellulose. In another example, the water-soluble polymer comprises starch. In yet another example, the water-soluble polymer comprises polyvinyl alcohol and starch.

Microorganisms

The filaments of the present invention comprise one or more microorganisms. The microorganisms may be selected from the group consisting of: prokaryotes, eukaryotes, viruses, bacteriophages, and mixtures thereof. Non-limiting examples of prokaryotes include bacteria and archaea. Non-limiting examples of eukaryotes include fungi.

Bacteria

Bacteria suitable for use in the present invention include gram-positive cocci, gram-positive bacilli and gram-negative baccili. Non-limiting example of bacteria for use in the filaments of the present invention include microbes isolated from human and animal microbiota (the aggregate of microorganisms that reside on the surface and in deep layers of skin, in the saliva, in the oral mucosa, in the vaginal mucosa, in the conjunctiva, and in the gastrointestinal tracts.

In one example, the bacteria is a probiotic.

A probiotic is a bacteria that provides a beneficial health and/or welfare effect on its host, such as humans and/or animals. Non-limiting examples of probiotics for use in the filaments of the present invention include Bifidobacteria species, Lactobacillus species, Lactococcus species,

Pediococcus species, Leuconostoc species, Sporolactobacillus species, and Bacillus species and mixtures thereof.

Non-limiting examples of Bifidobacteria species include Bifidobacterium adolescentis, Bifidobacterium bifidum, Bifidobacterium animalis, Bifidobacterium thermophilum, Bifidobacterium breve, Bifidobacterium ion gum, Bifidobacterium infantis and Bifidobacterium lactis. Specific strains of Bifidobacteria useful as probiotics include Bifidobacterium breve strain Yakult, Bifidobacterium breve R070, Bifidobacterium lactis Bb12, Bifidobacterium longum R023, Bifidobacterium bifidum R071, Bifidobacterium infantis 35624, Bifidobacterium infantis R033, Bifidobacterium longum BB536, Bifidobacterium animalis AHC7, and Bifidobacterium longum SBT-2928.

Non-limiting examples of Lactobacillus species for use in the filaments of the present invention include Lactobacillus sporogenes, Lactobacillus jensenii, Lactobacillus vaginalis, , Lactobacillus gallinarum, Lactobacillus coleohominis, and Lactobacillus iners, Lactobacillus bulgaricus, Lactobacillus cereale, Lactobacillus delbrukeii, Lactobacillus rhamnosus, Lactobacillus thermophilus, Lactobacillus paracasai sp. paracasai, Lactobacillus helveticus, Lactobacillus acidophilus, Lactobacillus brevis, Lactobacillus ulgaricus, Lactobacillus casei, Lactobacillus cellobiosus, Lactobacillus crispatus, Lactobacillus curvatus, Lactobacillus fermentum, Lactobacillus GG (Lactobacillus rhamnosus or Lactobacillus casei subspecies rhamnosus), Lactobacillus gasseri, Lactobacillus johnsonii, Lactobacillus plantarum, Lactobacillus reuteri, Lactobacillus salivarius, and mixtures thereof. Lactobacillus plantarum 299v strain originates from sour dough. Lactobacillus plantarum itself is of human origin. Other probiotic strains of Lactobacillus are Lactobacillus acidophilus BG2FO4, Lactobacillus acidophilus INT-9, Lactobacillus plantarum ST3 1, Lactobacillus reuteri, Lactobacillus johnsonii LA1, Lactobacillus acidophilus NCFB 1748, Lactobacillus casei Ski rota, Lactobacillus acidophilus NCFM, Lactobacillus acidophilus DDS-1, Lactobacillus delbrueckii subspecies delbrueckii, Lactobacillus delbrueckii subspecies bulgaricus type 2038, Lactobacillus acidophilus SBT-2062, Lactobacillus brevis, Lactobacillus salivarius UCC 118, Lactobacillus fermentum 297R1, Lactobacillus reuteri Grant L1, Lactobacillus crispatus 330L1, Lactobacillus and Lactobacillus paracasei subsp paracasei F 19. In one example the microorganism comprises a species of Lactobacillus include L. caesi, L. acidophilus, L. plantarum, and L. rhamnosus.

A non-limiting examples of Lactococcus species for use in the filaments of the present invention includes Lactococcus lactis.

Non-limiting examples of Pediococcus species for use in the filaments of the present invention include Pediococcus acidilactici, Pedioccocus pentosaceus, Pedioccocus urinae, and mixtures thereof.

A non-limiting example of a Leuconostoc species for use in the filaments of the present invention includes Leuconostoc mesenteroides.

A non-limiting example of a Sporolactobacillus species for use in the filaments of the present invention includes Sporolactobacillus inulinus.

Non-limiting examples of Bacillus species for use in the filaments of the present invention include Bacillus coagulans, Bacillus subtilis, Bacillus laterosporus, Bacillus laevolacticus, and mixtures thereof.

Other probiotic microbes that may be present in the filaments of the present invention include the gram-positive facultative anaerobe Streptococcus thermophilus, Enterococcusfaecium SF68.

In one example, the probiotic is BifantisTM35624 (bifido bactierium, Chr. Hansen, Denmark) and/or Bifidobacterium infantis 35624. Non-limiting examples of other suitable probiotics include probiotics from strains of Bifidobacterium isolated from resected and washed human gastrointestinal tract. An example includes Bifidobacterium infantis strain designated UCC35624, described as being deposited at the National Collections of Industrial and Marine Bacteria Ltd (NCIMB) on Jan. 13, 1999, and accorded the accession number NCIMB 41003 and described in U.S. Pat. No. 7,195,906. Suitable examples of probiotics useful herein comprise strains of Bifidobacterium longum infantis (NCIMB 35624), Lactobacillus johnsonii (CNCM 1-1225), Bifidobacterium lactis (DSM20215), Lactobacillus paracasei (CNCM 1-2216), and mixtures thereof. Further non-limiting examples of probiotics useful herein are described in WO 03/010297 Al, WO 03/010298 Al, WO 03/010299 Al (all published Feb. 6, 2003 and assigned to Alimentary Health Ltd) and US Patent Application Publication No. US2012/0276143.

In one example, the probiotic comprises Bifidobacterium strain AH1714 and/or Bifidobacterium longum strain UCC35624. A deposit of Bifidobacterium longum strain AH1714 was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) Ferguson Building, Craibstone Estate, Bucksbum, Aberdeen, AB21 9YA, Scotland, UK on Nov. 5, 2009 and accorded the accession number NCIMB 41676. A deposit of Bifidobacterium longum strain UCC35624 was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) Ferguson Building, Craibstone Estate, Bucksburn, Aberdeen, AB21 9YA, Scotland, UK on Jan. 13, 1999 and accorded the accession number NCIMB 41003. The Bifidobacterium longum strain may be a genetically modified mutant or it may be a naturally

occurring variant thereof. In one example, the Bifidobacterium longum strain is in the form of viable cells. In another example, the Bifidobacterium longum strain is in the form of non-viable cells

In another example, the probiotic comprises Bifidobacterium strain AH121A. A deposit of Bifidobacterium longum strain AH121A was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) Ferguson Building, Craibstone Estate, Bucksburn, Aberdeen, AB21 9YA, Scotland, UK on Nov. 5, 2009 and accorded the accession number NCIMB 41675.

In another example, the probiotic comprises Bifidobacterium strain AH121A. A deposit of Bifidobacterium longum strain AH121A was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) Ferguson Building, Craibstone Estate, Bucksburn, Aberdeen, AB21 9YA, Scotland, UK on Nov. 5, 2009 and accorded the accession number NCIMB 41675.Non-limiting examples of microorganisms can include strains of Streptococcus lactis, Streptococcus cremoris,Streptococcus diacetylactis, Streptococcus thermophilus, Lactobacillus bulgaricus, Lactobacillus acidophilus (e.g., Lactobacillus acidophilus strain), Lactobacillus helveticus,Lactobacillus bifidus, Lactobacillus casei, Lactobacillus lactis, Lactobacillus plantarum, Lactobacillus rhamnosus,Lactobacillus delbruekii, Lactobacillus thermophilus,Lactobacillus fermentii, Lactobacillus salivarius, Lactobacillus reuteri, Bifidobacterium longum, Bifidobacterium infantis, Bifidobacterium bifidum, Bifidobacterium animalis,Bifidobacterium pseudolongum, Saccharomyces boulardii,Pediococcus cerevisiae, Lactobacillus salivarius, Bacillus coagulans, and combinations thereof. Such probiotics, in one example, can be present in the filaments of the present invention at from about 0.025% to about 10% and/or from about 0.025% to about 5% and/or from about 0.025% to about 3% and/or from about 0.025% to about 1%, by weight on a dry filament basis.

<u>Fungi</u>

Non-limiting examples of suitable fungi for use in the filaments of the present invention include Penicillum, Saccharomyces cerevisiae, and mixtures thereof.

<u>Viruses</u>

Suitable virues for use in the filaments of the present invention include all 7 groups of viruses. These include Group I : double-stranded DNA viruses; Group II : single-stranded DNA viruses; Group III : double-stranded RNA viruses; Group IV : positive-sense single-stranded RNA viruses; Group V : negative-sense single-stranded RNA viruses; Group VI : reverse

transcribing RNA viruses and Group VII : reverse transcribing DNA viruses. Non-limiting examples include vaccines for human and animals.

Bacteriophages

Suitable bacteriophages for use in the filaments of the present invention include Salmonella, E.coli, Pseudomonas, Bacillus, Listeria, Burkholderia, S. aureus, and S. mutans phages.

Prebiotics

In addition to one or more microorganisms, the filaments of the present invention may further comprise one or more prebiotics.

Non-limiting examples of suitable prebiotics include inulin, lactose, raffinose, stachyose, fructo-oligossacharides, gluco-oligosaccharides, lactoferrin, mannan oligosaccharides, glucan oligosaccharides, isomalto-oligosaccharides, lactosucrose, polydextrose, soybean oligosaccharides, xylo-oligosaccharides, and mixtures thereof.

Other non-limiting examples of suitable prebiotics include human milk oligosaccharides as disclosed in US2013281948 A1, for example lactose, 2'-fucosyllactose, 3'-fucosyllactose, difucosyllactose, lacto-N-tetraose (type 1), lacto-N-neo-tetraose (type 2), lacto-N-fucopentaoses I, II, III, IV and V, lacto-N-fucohexaose I, lacto-N-hexaose, lacto-N-neohexaose, fucosyllacto-Nhexaose I and IV, fucosyllacto-N-neohexaose, lacto-N-difuco-hexaoses I and II, lacto-Noctaoses, sialya2-3lactose, sialya2-6lactose, sialyl-lacto-N-tetraose a, b and c, and disialyl-lacto-N-tetraose, and mixtures thereof.

Still other non-limiting examples of suitable prebiotics include fucose-a(1®2)galalactose b as a disaccharide unit, 2'-fucosyllactose, 3'-fucosyllactose, lacto-N-difuco-tetraose, lacto-N-difuco-hexose I, lacto- N-difuco-hexose II, lacto-N-fucopentaose I, lacto-N-fucopentaose II, lacto-N-fucopentaose III, lacto-N-fucopentaose V, and mixtures thereof.

In one example, the prebiotics may comprise carob bean, citrus pectin, rice bran, locust bean, fructooligosaccharide, oligofructose, galactooligosaccharide, citrus pulp, annanoligosaccharides, arabinogalactan, lactosucrose, glucomannan, polydextrose, apple pomace, tomato pomace, carrot pomace, cassia gum, gum karaya, gum talha, gum arabic, and combinations thereof. Such prebiotics, in one example, may be present in the filaments of the present invention at from about 1% to about 85% and/or from about 10% to about 60% and/or from about 20% to about 50% by weight on a dry filament basis.

Stabilizing Agents

The filaments of the present invention may comprise one or more stabilizing agents. When present in the filament, the stabilizing agents may be present in the filament at a level of from about 0% to about 60% and/or from about 10% to about 50% by weight on a dry filament basis.

The stabilizing agent may comprise a carbohydrate and/or a protein. The carbohydrate may be present in the filaments at a level of from about 0% to about 50% and/or from about 10% to about 40% by weight on a dry filament basis. The carbohydrate may be selected from the group consisting of: monosaccharides, disaccharides, oligosaccharides, polysaccharides, and mixtures thereof. Non-limiting examples of suitable carbohydrates include sucrose, trehalose, glycerol, glucose, mannitol, sorbitol, adonitol, betaine (N,N,N-trimethylglycine), lactose, fructo-oligosaccharides (FOS), polyfructoses, for example, inulin, pectin, 6-glucans, resistant starches, for example high amylose starch, dextrans, acacia gum, guar and locust bean gum, agar, carrageenans, xanthan and maltodextrins, and mixtures thereof.

The protein may be present in the filaments at a level of from about 0% to about 30% and/or from about 1% to about 20% by weight on a dry filament basis. The protein may be selected from the group consisting of albumen, arginine/lysine polypeptide, collagen and hydrolyzed collagen, gelatin and hydrolyzed gelatin, glycoproteins, milk protein, casein, such as sodium caseinate, whey protein, soy protein, barley protein, serum albumin, meat, fish, seafood, poultry, egg proteins, silk, soybean, corn, peanut, cottonseed, sunflower, pea, wheat protein, wheat germ protein, gluten-protein, zein and any isolate or hydrolyzed of any vegetable protein, such as soy protein isolate and/or hydrosylate, barley protein isolate and/or hydrosylate, and mixtures thereof.

Antioxidants

The filaments of the present invention may comprise one or more antioxidants. When present, the antioxidants may be present in the filament at a level of from about 0.01% to about 1% and/or from about 0.1% to about 0.5% and/or from about 0.1% to about 0.2% by weight on a dry filament basis.

Non-limiting examples of antioxidants that may be present in the filaments of the present invention include the following.

Rice bran derivatives have been shown to have more than a hundred (100) potent anti-oxidants including vitamin E and its isomers (tocopherols (T) and tocotrienols (T3)), collectively referred to as tocols. A tocol-rich substance is a mixture containing one or more compounds selected from tocopherols (T), tocotrienols, and tocotrienollike (T3 -like) compounds. Stabilized rice bran is the highest natural source of vitamin E.

Additional antioxidants in stabilized rice bran derivatives include, but are not limited to, y-oryzanol, (3-carotene, several known flavanoids, phytosterols, lipoic acid, ferulic acid and inositol hexaphospate (i.e., "IP6"). Some of these compounds are present in stabilized rice bran derivatives at concentrations which are much higher than in any of the known natural sources of the compounds. Ferulic acid, for example, is a phytochemical found in seeds of plants such as in brown rice, whole wheat and oats, as well as in coffee, apple, artichoke, peanut, orange and pineapple. Ferulic acid protects our cells form ultraviolet rays and neutralizes reactive oxygen species in the body, thereby preventing the reactive oxygen species from causing damage to our DNA. Being an antioxidant, it also reduces the level of cholesterol and triglyceride in the body and thus lowers the risk of heart diseases. IP6 is a phosphorylated form of inositol commonly found in fiber-rich plant foods. IP6 is hydrolyzed by phytase enzymes in the digestive tract to yield inositol. IP6 supports a cell's natural defense against damaging hydroxyl free radicals by chelating with reactive iron. In combination with probiotics, antioxidants provide exceptional additional defense and increase the immune system's ability to resist invasive pathogens associated with gastrointestinal disorders.

In one example, the antioxidants present in the filaments may be selected from the group consisting of: carotenoids, such as lycopene, beta-carotene, lutein, xanthophylls, vitamin A, tocopherols, vitamin C, and mixtures thereof.

In another example, the antioxidants present in the filaments may be selected from the group consisting of propyl gallate, butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), Vitamin C, Vitamin A, Vitamin E, beta-carotene, and mixtures thereof.

Dietary Fibers

The filaments and/or webs of the present invention may further comprise dietary fibers. Non-limiting examples of dietary fibers can include, but are not limited to inulin, agar, beta-glucans, chitins, dextrins, lignin, cellulose, modified cellulose, cellulose ethers, hemicelluloses, non-starch polysaccharides, reduced starch, polycarbophil, partially hydrolyzed guar gum, wheat dextrin, and combinations thereof.

Optional Additives

The filament-forming composition and filament made therefrom and ultimately the web comprising such filaments may comprise optional additives, such as

Method for Making Filament

The filaments of the present invention are produced by spinning a filament-forming composition comprising one or more filament-forming materials and one or more microorganisms.

In one example, as shown in Fig. 2, a method 14 for making a filament 10 of the present invention comprises the steps of:

a. providing a filament-forming composition 16, for example a filament-forming liquid composition suitable for making filaments, comprising one or more filament-forming materials, one or more microorganisms, and one or more stabilizing agents, from a source 18, such as a tank, for example a pressurized tank suitable for batch operations; and

b. spinning the filament-forming composition 16 from a die 20, such as a meltblow die, to produce one or more filaments 10 of the present invention.

The filament-forming composition 16 may be in fluid communication with the die 20 via suitable piping 22 as shown with the arrows. A pump 24 (for example a Zenith®, type PEP II pump having a capacity of 5.0 cubic centimeters per revolution (cc/rev), manufactured by Parker Hannifin Corporation, Zenith Pumps division, of Sanford, N.C., USA) may be used to pump the filament-forming composition 16 to the die 20. The filament-forming composition's 16 flow to the die 20 may be controlled by adjusting the flowrate of the pump 20.

The die 20 as shown in Fig. 3 may comprise two or more rows of circular extrusion nozzles 26 spaced from one another at a pitch P of about 1.524 millimeters (about 0.060 inches). The nozzles 26 may have individual inner diameters of about 0.305 millimeters (about 0.012 inches) and individual outside diameters of about 0.813 millimeters (about 0.032 inches). Each individual nozzle 26 may be encircled by an annular and divergently flared orifice 28 to supply attenuation air formed by mixing steam and heated compressed air to each individual nozzle 26. The filament-forming composition 16 that is extruded through the nozzles 26 is surrounded and attenuated by generally cylindrical, attenuation air streams supplied through the orifices 28 encircling the nozzles 26 to produce the filaments 10. The filaments 10 may be dried by a drying air stream having a temperature of from about 50° C to about 315° C by an electrical resistance heater 30 supplied through drying nozzles 32 and discharged at an angle of about 90° relative to the general orientation of the filaments 10 being spun.

During spinning of the filament-forming composition, the filament-forming composition and microorganisms contained therein are subjected to steam and attenuation air and drying air at temperatures of up to 450°C without negatively impacting the viability of the microorganisms, for example with less than a 3 and/or less than 2 and/or less than 1 log loss in viability.

The filaments 10 may be collected on a collection device, such as a belt or fabric, in one example a belt or fabric capable of imparting a pattern, for example a non-random repeating pattern to a web formed as a result of collecting the filaments on the belt or fabric.

In one example, the step of spinning may comprise contacting the filament with attenuation air to attenuate the filament.

The method may further comprise the step of collecting a plurality of filaments on a collection device, for example a spool or a belt or fabric, such as a patterned belt. Filaments may be collected and stored in desiccated flip top vials (commercially available from Desican Inc) and refrigerated until use.

The filaments of the present invention may exhibit an average diameter of greater than 1μm and/or greater than 3μm and/or greater than 5μm and/or less than 100μm and/or less than 70 μm.

In one example, the method of the present invention is a non-electrospinning method.

Non-limiting Example

A non-limiting example of a web comprising filaments according to the present invention is produced by using the method 14 shown in Figs. 2 and 3 as described above.

A non-limiting example of a filament-forming composition 16 according to the present invention is shown in Table 1 below

Ingredients of Filament-Forming Composition	Level (grams)
Antioxidant[1]	0.06
Stabilizing Agent[2]	4.29
Buffering Agent[3]	0.15
Protein[4]	1.53
Distilled Water	54.53
Microorganism[5]	1.86
Filament-forming Material[6]	10.88
Viability	

Initial Probiotic (Normalized at 10% Add-on) (log CFU/g)	9.92
Unprotected Probiotic After Aging 25°C/60% RH for 28 days (log CFU/g)	7.27
Unprotected Probiotic After Aging 25°C/60% RH for 56 days (log CFU/g)	4.57
Probiotic in Web After Spinning Process (log CFU/g)	9.2
Probiotic in Web After Aging 25°C/60% RH for 28 days (log CFU/g)	8.58
Probiotic in Web After Aging 25°C/60% RH for 56 days (log CFU/g)	7.74
Viability Log Loss (Initial – Condition)	
Unprotected Probiotic After Aging 25°C/60% RH for 28 days (log CFU/g)	2.65
Unprotected Probiotic After Aging 25°C/60% RH for 56 days (log CFU/g)	5.35
Probiotic in Web After Spinning Process (log CFU/g)	0.72
Probiotic in Web After Aging 25°C/60% RH for 28 days (log CFU/g)	1.34
Probiotic in Web After Aging 25°C/60% RH for 56 days (log CFU/g)	2.18
Physical Properties of Web	
Disintegration of Web	< 1 second
Dissolution of Web	10 minutes 27 seconds
Diameter of Fibrous Element in Web	20.85 microns ±

	7.72 microns

[1]Propyl gallate (Spectrum Chemicals, Gardena, CA)
[2]Trehalose (Swanson Ultra, Fargo, ND)
[3]Sodium Citrate Dehydrate (Sigma Aldrich, St. Louis, MO)
[4]Sodium Caseinate (Sigma Aldrich, St. Louis, MO)
[5]*L. fermentum*
[6]Polyvinyl alcohol (Sekisui Specialty Chemical Company, Dallas, TX)

Table 1

The filament-forming composition shown above in the non-limiting Example is prepared as follows:

1. Make up a polyvinyl alcohol solution of 23% polyvinyl alcohol by setting up a wide mouth pint jar in a water bath with over head stirrer fitted through a holed lid and a stir blade nearly as wide as the jar. Next, add 231g distilled water. With moderate stirring, slowly add 69g polyvinyl alcohol. Turn on water bath and heat to 70°C. When all of the polyvinyl alcohol is dissolved, turn off heat and allow to cool to 50°C. Remove from stirrer, cap, allow to sit sealed while cooling to 23°C. All of the air bubbles will be removed as it sits.

2. Make up a stock cryoprotecting solution at 25% solids.

Ingredients	% in Formula	Amount (g) for a 200g batch
Propyl gallate	0.23%	0.46
Trehalose	17.77%	35.54
Sodium citrate dihydrate	0.64%	1.28
Sodium caseinate	6.36%	12.72
Distilled water	75%	150

Dissolve all ingredients except sodium caseinate in 75mL distilled water by heating to 60°C with stirring to form a trehalose solution.

Disperse the sodium caseinate in 75mL distilled water and heat to 60°C to form a caseinate solution. Autoclave the caseinate solution at 121°C for 60 minutes and then cool to 23°C.

When cooled pour trehalose solution into caseinate solution. Bring weight to 200g by rinsing trehalose solution jar. Result is 25% solids. Seal and store in refrigerator.

Next, make a filament-forming solution as follows:

1. Using a SpeedMixer or equivalent, mix 27.3g cryoprotectant solution with 1.86g probiotic for 4 minutes at 3500 rpm.

2. Again, using a SpeedMixer or equivalent, add 26g of the resulting mixture from step 1

with 47.3g of the polyvinyl alcohol solution from above by mixing 4 min @ 3500 rpm.

3. Transfer resulting solution to filament spinning apparatus as shown in Fig. 2 syringe pump reservoir. Close, attach piping; begin the filament spinning apparatus air flow and heaters. Begin solution addition. Collect fibers and place into a glass jar and seal.

Initial Filament Spinning Apparatus Settings

Wall Att'n	Wall Dry Air #1, #2	Electric Panel Temperature Settings Degrees Centigrade			Flow Meters on Test Stand SCFM			Steam Needle Valve	Fluid Flow Rate
psi	psi	Att'n Air	Dry Air #1	Dry Air #2	Att'n Air	Dry Air #1	Dry Air #2	Turns Open	Ml/min
20	30	65	300	300	3.8	5.8	5.6	Off	1.0-1.6

Test Methods

Viability/Count Test Method

Viability of microorganisms in web comprising a filament comprising one or more microorganisms is determined as follows.

Sample Preparation

Webs comprising filaments to be tested are removed from any protective packaging. One or more filaments to be tested are removed from the web. Filaments are tested neat (without any protective packaging such as blister packs or other similar packaging). The filaments to be tested are conditioned at 30°C +/- 2°C and 30% +/- 2% relative humidity in an open container for 28 and 56 days prior to testing and then tested immediately after the 28 or 56 days of conditioning. In addition, the filaments to be tested are conditioned at 25°C +/- 2°C and 60% +/- 2% relative humidity in an open container for 28 and 56 days prior to testing and then tested immediately after the 28 or 56 days of conditioning.

Testing Procedure

1. Dissolve 2.0 g of a filament comprising one or more microorganisms into 18 mL of a general purpose medium selected according to microorganism being tested, for example, but not limited to, sterile TSB (tryptic soy broth) (1:10 dilution) (Accumedia Manufacturers Inc. of

Lansing, MI) in a 100 mL beaker and vortex for 10 minutes using a magnetic stirrer (Labline Model No. 1250 or equivalent) and magnetic stirring rod (5 cm) to form a concentrated microorganism suspension.

2. Make serial dilutions of the concentrated microorganism suspension from Step 1 above using TSB medium up to -8 (1:100000000).

3. Spiral Plating the serial dilutions from Step 2 above with an AutoPlate 4000 or 5000 Automated Spiral Plater from Spiral Biotech or a similar instrument is used for the plating of prepared serial dilutions on pre-poured petri plates selected according to microorganism being tested, for example, but not limited to Agar gel petri plates, (20-25mL per plate). The dilution series prepared from the above methods are each individually plated according to the standard spiral plating method known in the art in duplicate. The plater dispenses 50µL of each serial dilution circularly across the petri plate surface.

4. Invert each plate and incubate at 35°C (+/-2 °C) for 48 (+/-4) hours to 72 hours, under anaerobic conditions in an anaerobe chamber or anaerobe box or aerobic conditions in an aerobic chamber or aerobic box depending on what microorganism being tested.

5. At the end of the incubation period (Step 4 above) remove each plate and count CFUs using Q-Count from Spiral Biotech.

6. The total count (total level) of a microorganism present in the filament (CFU/gram of filament) is calculated based on weight of the filament used, the CFU count of the microorganism obtained from the Q-Count software, and the dilution factor if the Q-Count software doesn't automatically factor in the dilution factor.

The log loss value is calculated as the difference between the final count of microorganisms (CFU/gram of filament) and the initial count of microorganisms added to the filament-forming composition that produced the filament (CFU/gram of filament). If the initial count of microorganisms is not known to the tester, then the difference between the final count of microorganisms (CFU/gram of filament) conditioned at 30°C +/- 2°C and 30% +/- 2% relative humidity for 28 days prior to testing and the final count of microorganisms (CFU/gram of filament) conditioned at 23°C +/- 2.2°C and 50% +/- 10% relative humidity for 2 hours (an estimate of the initial count until the actual initial count is obtained).

Diameter Test Method

The average diameter of a discrete filament or a filament within a web or film is determined by using a Scanning Electron Microscope (SEM) or an Optical Microscope and an image analysis software. A magnification of 200 to 10,000 times is chosen such that the

filaments are suitably enlarged for measurement. When using the SEM, the samples are sputtered with gold or a palladium compound to avoid electric charging and vibrations of the filament in the electron beam. A manual procedure for determining the filament diameters is used from the image (on monitor screen) taken with the SEM or the optical microscope. Using a mouse and a cursor tool, the edge of a randomly selected filament is sought and then measured across its width (i.e., perpendicular to filament direction at that point) to the other edge of the filament. A scaled and calibrated image analysis tool provides the scaling to get actual reading in μm. For filaments within a web or film, several filament are randomly selected across the sample of the web or film using the SEM or the optical microscope. At least two portions the web or film (or web inside a product) are cut and tested in this manner. Altogether at least 100 such measurements are made and then all data are recorded for statistical analysis. The recorded data are used to calculate average (mean) of the filament diameters, standard deviation of the filament diameters, and median of the filament diameters.

Dissolution Test Method

Apparatus and Materials (also, see Figs. 4-6):

600 mL Beaker 34

Magnetic Stirrer 36 (Labline Model No. 1250 or equivalent)

Magnetic Stirring Rod 38 (5 cm)

Thermometer (1 to 100°C +/- 1 °C)

Cutting Die -- Stainless Steel cutting die with dimensions 3.8 cm x 3.2 cm

Timer (accurate to at least 0.1 second)

Alligator clamp (about one inch long) 40

Depth adjuster rod 42 and holder 44 with base 46

Polaroid 35 mm Slide Mount (commercially available from Polaroid Corporation or equivalent) and 35 mm Slide Mount Holder (or equivalent) 48

Deionized water (equilibrated at 23°C ± 1°C) 50

Test Protocol

Equilibrate web samples in constant temperature and humidity environment of 23°C ± 1 °C and 50%RH ± 2% for at least 2 hours.

Measure the basis weight of a web sample to be tested using Basis Weight Method defined herein.

Cut three dissolution test specimens from the web sample using cutting die (3.8 cm x 3.2 cm), so it fits within the 35 mm slide mount 48 which has an open area dimensions 24 x 36 mm.

Lock each specimen in a separate 35 mm slide mount 48.

Place magnetic stirring rod 38 into the 600 mL beaker 34.

Fill beaker 34 with 500 mL ± 5 mL of the deionized water 50.

Place full beaker 34 on magnetic stirrer 36, turn on stirrer 36, and adjust stir speed until a vortex develops and the bottom of the vortex is at the 400 mL mark on the beaker 34.

A trial run may be necessary to ensure the depth adjuster rod 42 is set up properly. Secure the 35 mm slide mount 48 in the alligator clamp 40 of the 35 mm slide mount holder such that the long end of the slide mount is parallel to the water surface. The alligator clamp 40 should be positioned in the middle of the long end of the slide mount. The alligator claim 40 is soldiered to the end of a depth adjuster rod 42. The depth adjuster rod 42 is set up in a way, so that when the slide mount 48 is lowered into the water, the entire specimen is completely submerged in the water at the center of the beaker 34, the top of the specimen is at the bottom of the vortex, and the bottom of the slide mount/slide mount holder is not in direct contact with the stirring rod 38. The depth adjuster rod 42 and alligator clamp 40 should be set so that the position of the specimen's surface is perpendicular to the flow of the water.

In one motion, drop the secured slide and clamp into the water and start the timer. The specimen is dropped so that the specimen is centered in the beaker. Disintegration occurs when the specimen breaks apart. Record this as the disintegration time. When all of the visible specimen is released from the slide mount, raise the slide out of the water while continuing the monitor the solution for undissolved specimen fragments. Dissolution occurs when all specimen fragments are no longer visible. Record this as the dissolution time.

Three replicates of each web sample are run and the average disintegration and dissolution times are recorded. Average disintegration and dissolution times are in units of seconds.

The average disintegration and dissolution times are normalized for basis weight by dividing each by the sample basis weight as determined by the Basis Weight Method defined herein. Basis weight normalized disintegration and dissolution times are in units of seconds/gsm of sample (s/(g/m^2)).

Thickness Method

Thickness of a web is measured by cutting 5 samples of a web sample such that each cut sample is larger in size than a load foot loading surface of a VIR Electronic Thickness Tester

Model II available from Thwing-Albert Instrument Company, Philadelphia, PA. Typically, the load foot loading surface has a circular surface area of about 3.14 in^2. The web sample is confined between a horizontal flat surface and the load foot loading surface. The load foot loading surface applies a confining pressure to the sample of 15.5 g/cm^2. The caliper of each sample is the resulting gap between the flat surface and the load foot loading surface. The caliper is calculated as the average caliper of the five web samples. The result is reported in millimeters (mm).

Basis Weight Test Method

Basis weight of a web sample is measured by selecting twelve (12) individual web samples and making two stacks of six individual samples each. If the individual samples are connected to one another vie perforation lines, the perforation lines must be aligned on the same side when stacking the individual samples. A precision cutter is used to cut each stack into exactly 3.5 in. x 3.5 in. squares. The two stacks of cut squares are combined to make a basis weight pad of twelve squares thick. The basis weight pad is then weighed on a top loading balance with a minimum resolution of 0.01 g. The top loading balance must be protected from air drafts and other disturbances using a draft shield. Weights are recorded when the readings on the top loading balance become constant. The Basis Weight is calculated as follows:

$$\text{Basis Weight (lbs/3000 ft}^2\text{)} = \frac{\text{Weight of basis weight pad (g)} \times 3000\ ft^2}{453.6\ g/lbs \times 12\ samples \times [12.25 in^2\ (\text{Area of basis weight pad})/144\ in^2]}$$

$$\text{Basis Weight (g/m}^2\text{)} = \frac{\text{Weight of basis weight pad (g)} \times 10{,}000\ cm^2/m^2}{79.0321\ cm^2\ (\text{Area of basis weight pad}) \times 12\ \text{samples}}$$

Density Test Method

The density of a web sample is measured by dividing the Basis Weight of the web sample by the Thickness of the web sample. Density units are reported as g/cm^3.

Tensile Test Method: Peak Elongation, Tensile Strength, TEA and Modulus

Peak Elongation, Tensile Strength, TEA and Tangent Modulus are measured on a constant rate of extension tensile tester with computer interface (a suitable instrument is the EJA Vantage from the Thwing-Albert Instrument Co. Wet Berlin, NJ) using a load cell for which the forces measured are within 10% to 90% of the limit of the cell. Both the movable (upper) and stationary (lower) pneumatic jaws are fitted with smooth stainless steel faced grips, 25.4 mm in

height and wider than the width of the test specimen. An air pressure of about 60 psi is supplied to the jaws.

Eight usable units of a web sample are divided into two stacks of four samples each. The samples in each stack are consistently oriented with respect to machine direction (MD) and cross direction (CD). One of the stacks is designated for testing in the MD and the other for CD. Using a one inch precision cutter (Thwing Albert JDC-1-10, or similar) cut 4 MD strips from one stack, and 4 CD strips from the other, with dimensions of 1.00 in ± 0.01 in wide by 3.0 – 4.0 in long. Each strip of one usable unit thick will be treated as a unitary specimen for testing.

Program the tensile tester to perform an extension test, collecting force and extension data at an acquisition rate of 20 Hz as the crosshead raises at a rate of 2.00 in/min (5.08 cm/min) until the specimen breaks. The break sensitivity is set to 80%, i.e., the test is terminated when the measured force drops to 20% of the maximum peak force, after which the crosshead is returned to its original position.

Set the gauge length to 1.00 inch. Zero the crosshead and load cell. Insert at least 1.0 in of the unitary specimen into the upper grip, aligning it vertically within the upper and lower jaws and close the upper grips. Insert the unitary specimen into the lower grips and close. The unitary specimen should be under enough tension to eliminate any slack, but less than 5.0 g of force on the load cell. Start the tensile tester and data collection. Repeat testing in like fashion for all four CD and four MD unitary specimens.

Program the software to calculate the following from the constructed force (g) verses extension (in) curve:

Tensile Strength is the maximum peak force (g) divided by the sample width (in) and reported as g/in to the nearest 1 g/in.

Adjusted Gauge Length is calculated as the extension measured at 3.0 g of force (in) added to the original gauge length (in).

Peak Elongation is calculated as the extension at maximum peak force (in) divided by the Adjusted Gauge Length (in) multiplied by 100 and reported as % to the nearest 0.1%

Total Energy (TEA) is calculated as the area under the force curve integrated from zero extension to the extension at the maximum peak force (g*in), divided by the product of the adjusted Gauge Length (in) and specimen width (in) and is reported out to the nearest 1 g*in/in^2. Replot the force (g) verses extension (in) curve as a force (g) verses strain curve. Strain is herein defined as the extension (in) divided by the Adjusted Gauge Length (in).

Program the software to calculate the following from the constructed force (g) verses strain curve:

Tangent Modulus (Modulus) is the Modulus at 15 g/cm.

The Tensile Strength (g/in), Peak Elongation (%), Total Energy (g*in/in^2) and Modulus (g/cm), which is the Tangent Modulus at 15 g/cm), are calculated for the four CD unitary specimens and the four MD unitary specimens. Calculate an average for each parameter separately for the CD and MD specimens.

Calculations:

Geometric Mean Tensile Strength = Square Root of [MD Tensile Strength (g/in) x CD Tensile Strength (g/in)]

Geometric Mean Peak Elongation = Square Root of [MD Elongation (%) x CD Elongation (%)]

Geometric Mean TEA = Square Root of [MD TEA (g*in/in^2) x CD TEA (g*in/in^2)]

Geometric Mean Modulus = Square Root of [MD Modulus (g/cm) (at 15 g/cm) x CD Modulus (g/cm) (at 15 g/cm)]

Total Dry Tensile Strength (TDT) = MD Tensile Strength (g/in) + CD Tensile Strength (g/in)

Total TEA = MD TEA (g*in/in^2) + CD TEA (g*in/in^2)

Total Modulus = MD Modulus (g/cm) + CD Modulus (g/cm)

Tensile Ratio = MD Tensile Strength (g/in)/CD Tensile Strength (g/in)

Plate Stiffness Test Method

As used herein, the “Plate Stiffness” test is a measure of stiffness of a flat web sample as it is deformed downward into a hole beneath the sample. For the test, the web sample is modeled as an infinite plate with thickness “t” that resides on a flat surface where it is centered over a hole with radius “R”. A central force “F” applied to a web sample directly over the center of the hole deflects the web sample down into the hole by a distance “w”. For a linear elastic material the deflection can be predicted by:

$$w = \frac{3F}{4\pi E t^3}(1-v)(3+v)R^2$$

where “E” is the effective linear elastic modulus, “v” is the Poisson's ratio, “R” is the radius of the hole, and “t” is the thickness of the web sample, taken as the caliper in millimeters measured on a stack of 5 web samples under a load of about 0.29 psi. Taking Poisson's ratio as 0.1 (the solution is not highly sensitive to this parameter, so the inaccuracy due to the assumed value is

likely to be minor), the previous equation can be rewritten for "w" to estimate the effective modulus as a function of the flexibility test results:

$$E \approx \frac{3R^2}{4t^3} \frac{F}{w}$$

The test results are carried out using an MTS Alliance RT/1, Insight Renew, or similar model testing machine (MTS Systems Corp., Eden Prairie, Minn.), with a 50 Newton load cell, and data acquisition rate of at least 25force points per second. As a stack of five web samples (created without any bending, pressing, or straining) at least 2.5 inches by 2.5 inches, but no more than 5.0 inches by 5.0 inches, oriented in the same direction, sits centered over a hole of radius 15.75 mm on a support plate, a blunt probe of 3.15 mm radius descends at a speed of 20 mm/min. When the probe tip descends to 1 mm below the plane of the support plate, the test is terminated. The maximum slope (using least squares regression) in grams of force/mm over any 0.5 mm span during the test is recorded (this maximum slope generally occurs at the end of the stroke). The load cell monitors the applied force and the position of the probe tip relative to the plane of the support plate is also monitored. The peak load is recorded, and "E" is estimated using the above equation.

The Plate Stiffness "S" per unit width can then be calculated as:

$$S = \frac{Et^3}{12}$$

and is expressed in units of Newtons*millimeters. The Testworks program uses the following formula to calculate stiffness (or can be calculated manually from the raw data output):

$$S = \left(\frac{F}{w}\right)\left[\frac{(3+\nu)R^2}{16\pi}\right]$$

wherein "F/w" is max slope (force divided by deflection), "v" is Poisson's ratio taken as 0.1, and "R" is the ring radius.

The same 5-web sample stack (as used above) is then flipped upside down and retested in the same manner as previously described. This test is run three more times (with different sample stacks). Thus, eight S values are calculated from four 5-web sample stacks of the same web sample. The numerical average of these eight S values is reported as Plate Stiffness for the web sample.

Water Activity Test Method

A HygroPalm HP23-AW-A meter (commercially available from Rotronic AG of Bassersdorf, Switzerland) or equivalent is used to determine the water activity of materials. Consult the HygroPalm HP23-AW-A owner's manual for specific operating instructions (meter set-up and keystrokes for testing standards and samples).

1. Install the humidity probe onto the instrument.
2. Turn on the HygroPalm HP23-AW-A by pressing the red on/off button.
   a. Set the HygroPalm HP23-AW-A to the water activity AW Quick mode:
   b. Press the MENU key and select "AW Mode". Press ENTER to activate the AW Mode menu.
   c. With the "Enable" menu item highlighted, press ENTER and use the UP or DOWN arrow key to select ON. Press ENTER to confirm the selection.
   d. Use the DOWN arrow key to select the "Mode" menu item and press ENTER. Use the UP or DOWN arrow key to select AW Quick. Press ENTER to confirm the selection.
   e. Press MENU twice to fully exit the menu.
3. Fill sample cup 2/3 full with the material to be measured.
4. Place cup into sample holder base and fit top over the cup and base.
5. Press the appropriate button to start AW Quick data collection.
6. Start timer for 5 minutes. After 5 minutes, record AW from the HygroPalm HP23-AW-A.

The dimensions and values disclosed herein are not to be understood as being strictly limited to the exact numerical values recited. Instead, unless otherwise specified, each such dimension is intended to mean both the recited value and a functionally equivalent range surrounding that value. For example, a dimension disclosed as "40 μm" is intended to mean "about 40 μm."

Every document cited herein, including any cross referenced or related patent or application, is hereby incorporated herein by reference in its entirety unless expressly excluded or otherwise limited. The citation of any document is not an admission that it is prior art with respect to any invention disclosed or claimed herein or that it alone, or in any combination with any other reference or references, teaches, suggests or discloses any such invention. Further, to the extent that any meaning or definition of a term in this document conflicts with any meaning or definition of the same term in a document incorporated by reference, the meaning or definition assigned to that term in this document shall govern.

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

CLAIMS

What is claimed is:

1. A web comprising one or more fibrous elements wherein at least one of the fibrous elements comprises one or more filament-forming materials and one or more microorganisms, wherein at least one of the microorganisms exhibits at least one of the following: less than a 2.5 log viability loss after being exposed to 25°C/60% RH conditions for 28 days as measured according to the Viability/Count Test Method and less than a 5 log viability loss after being exposed to 25°C/60% RH conditions for 56 days as measured according to the Viability/Count Test Method.

2. The web according to Claim 1 wherein at least one microorganism is releasable from the fibrous element when exposed to conditions of intended use.

3. The web according to any of the preceding claims wherein the at least one microorganism is selected from the group consisting of: prokaryotes, eukaryotes, viruses, bacteriophages, and mixtures thereof.

4. The web according to any of the preceding claims wherein at least one of the microorganisms comprises a probiotic.

5. The web according to any of the preceding claims wherein at least one of the microorganisms comprises a labile microorganism.

6. The web according to any of the preceding claims wherein the filament-forming material is selected from the group consisting of: polyvinyl alcohol, polyvinyl alcohol derivatives, polyethylene oxide, starch, starch derivatives, cellulose, cellulose derivatives, carboxymethyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, sodium alginate, xanthan gum, tragacanth gum, guar gum, acacia gum, Arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, chitosan, chitosan derivatives, polyethylene glycol, hemicellulose, hemicelluloses derivatives, polyacrylamide, and copolymers and mixtures thereof.

7. The web according to any of the preceding claims wherein the fibrous element further comprises a stabilizing agent, preferably wherein the stabilizing agent is selected from the group consisting of carbohydrates, proteins, and mixtures thereof.

8. The web according to any of the preceding claims wherein the fibrous element further comprises an antioxidant, preferably wherein the antioxidant is selected from the group consisting of: propyl gallate, BHT, BHA,Vitamin C, Vitamin A, Vitamin E, beta-carotene and mixtures thereof.

9. The web according to any of the preceding claims wherein the fibrous element further comprises a plasticizer.

10. The web according to any of the preceding claims wherein the web is water-soluble.

11. The web according to any of the preceding claims wherein the fibrous element exhibits an average diameter of greater than 1µm as measured according to the Diameter Test Method.

12. The web according to any of the preceding claims wherein the fibrous element comprises a filament.

13. The web according to any of the preceding claims wherein the web exhibits a property selected from the group consisting of:

a. a GM Peak Elongation of greater than 5% as measured according to the Tensile Test Method;
b. a GM Tensile Strength of greater than 200 g/in as measured according to the Tensile Test Method;
c. a GM Modulus of less than 20,000 g/cm at 15 g/cm as measured according to the Tensile Test Method;
d. a Density of less than 0.50 g/cm^3 as measured according to the Density Test Method;
e. a Thickness of greater than 0.01 mm as measured according to the Thickness Test Method;
f. a water activity of less than 0.2 as measured according to the Water Activity Test Method;
g. an average Disintegration Time of less than 1 hour as measured according to the Dissolution Test Method;
h. an average Dissolution Time of less than 12 hours as measured according to the Dissolution Test Method;

i. a Basis Weight of less than 5000 g/m^2 as measured according to the Basis Weight Test Method; and

j. combinations thereof.

14. The web according to any of the preceding claims wherein at least one of the fibrous elements comprises a bicomponent filament.

15. A disposable absorbent article comprising a web according to any of the preceding claims, preferably wherein the disposable absorbent article is selected from the group consisting of: feminine hygiene pads, pantiliners, tampons, sanitary napkins, adult incontinence pads, adult incontinence pants, diapers, baby pants, toddler pants, overnight pants, swim pants, and mixtures thereof.

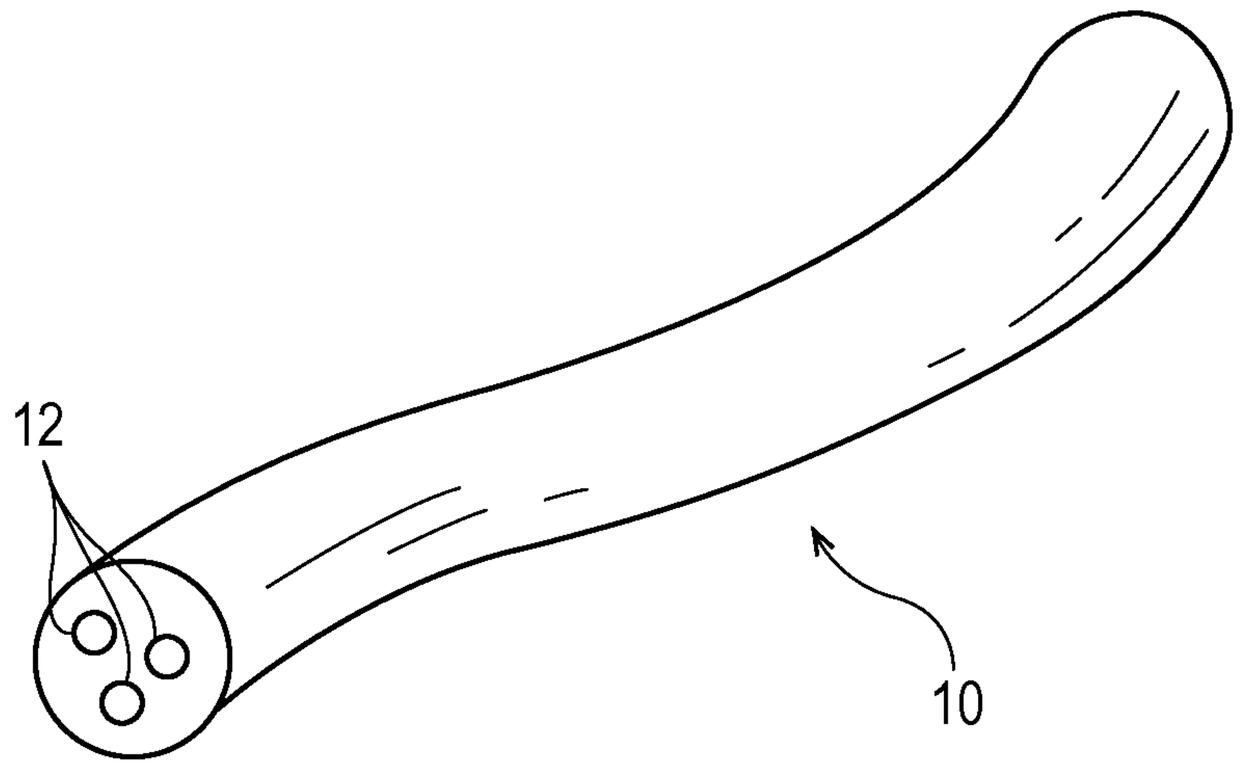

Fig. 1

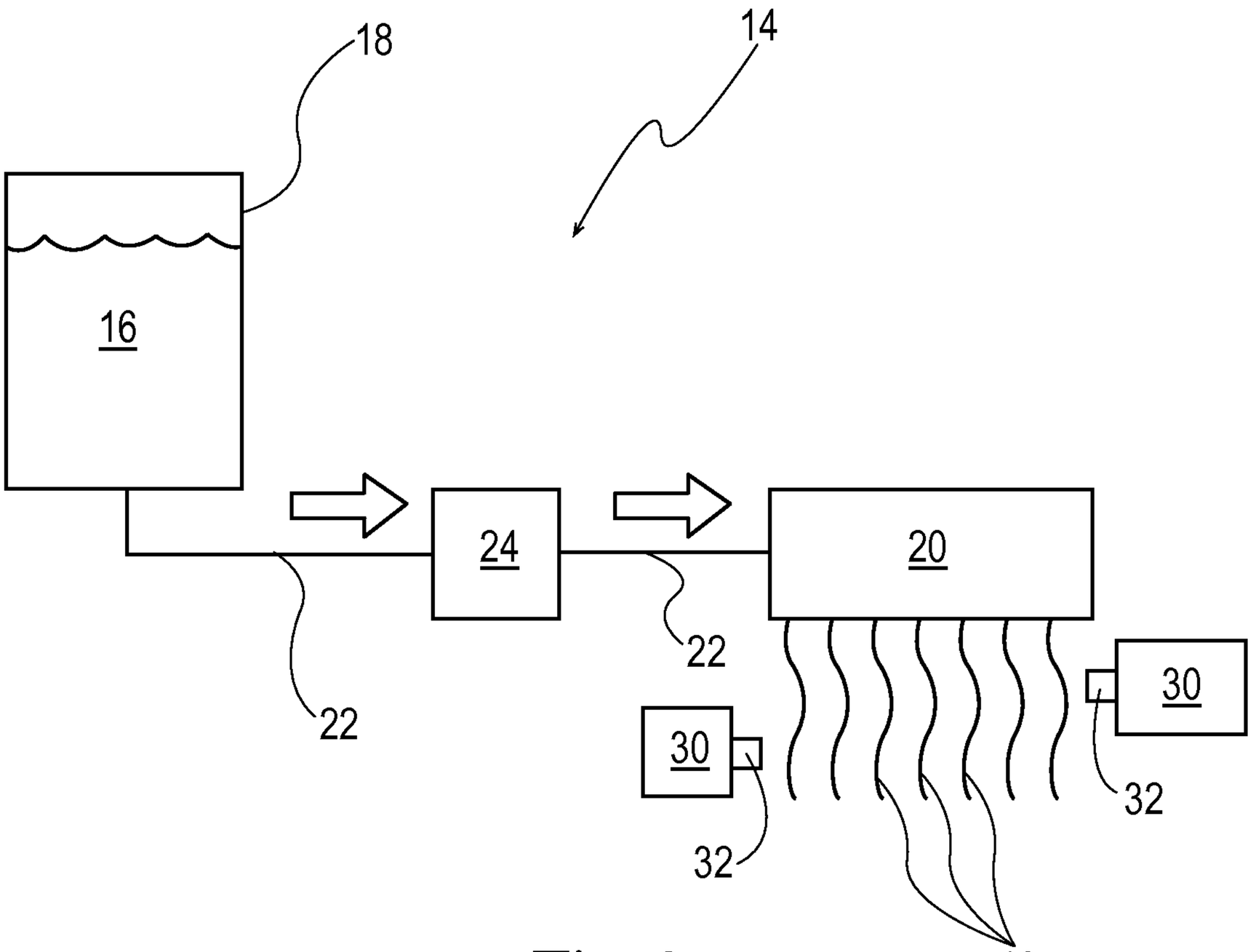

Fig. 2

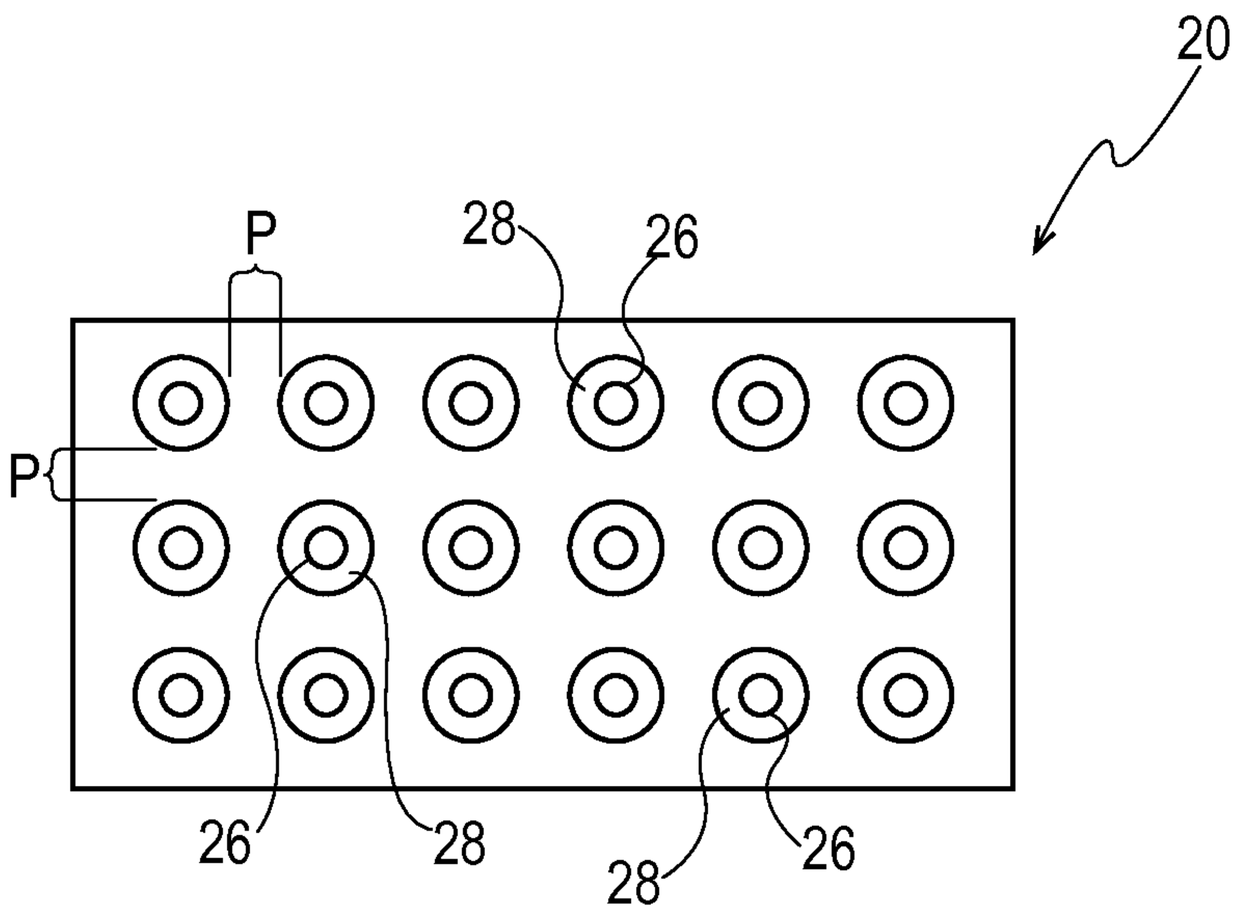

Fig. 3

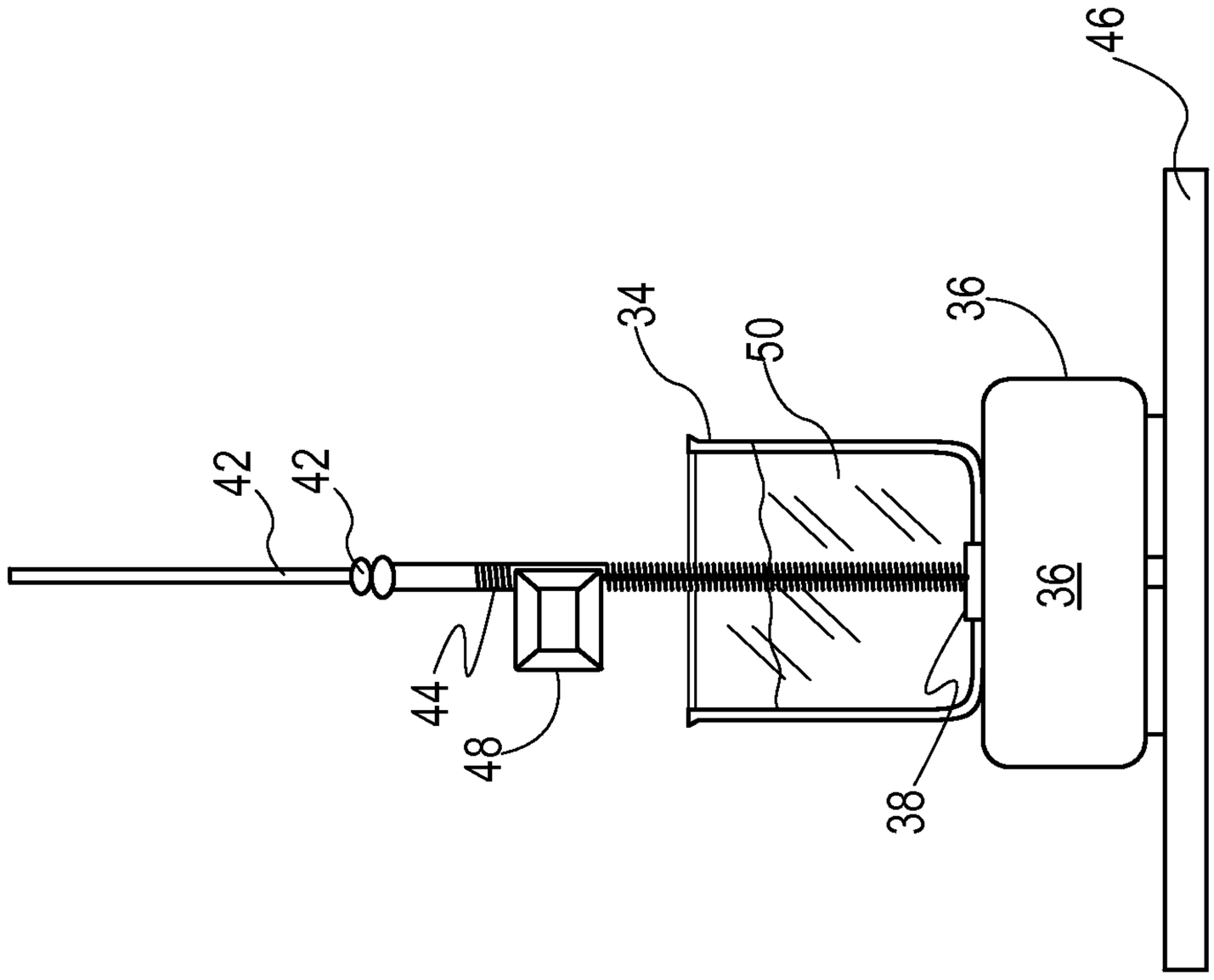

Fig. 6

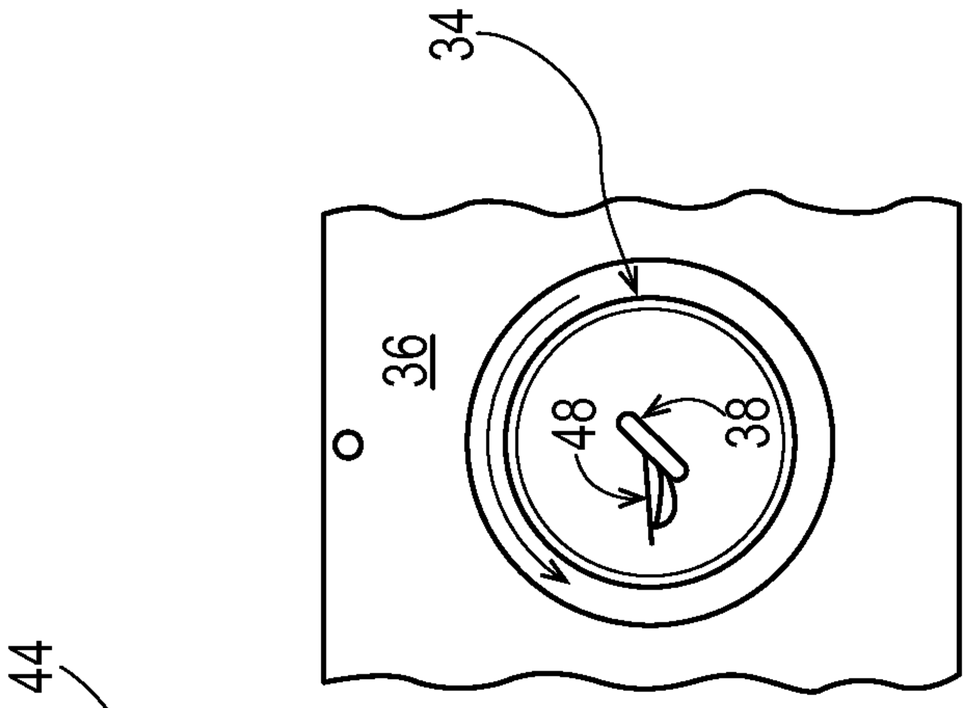

Fig. 5

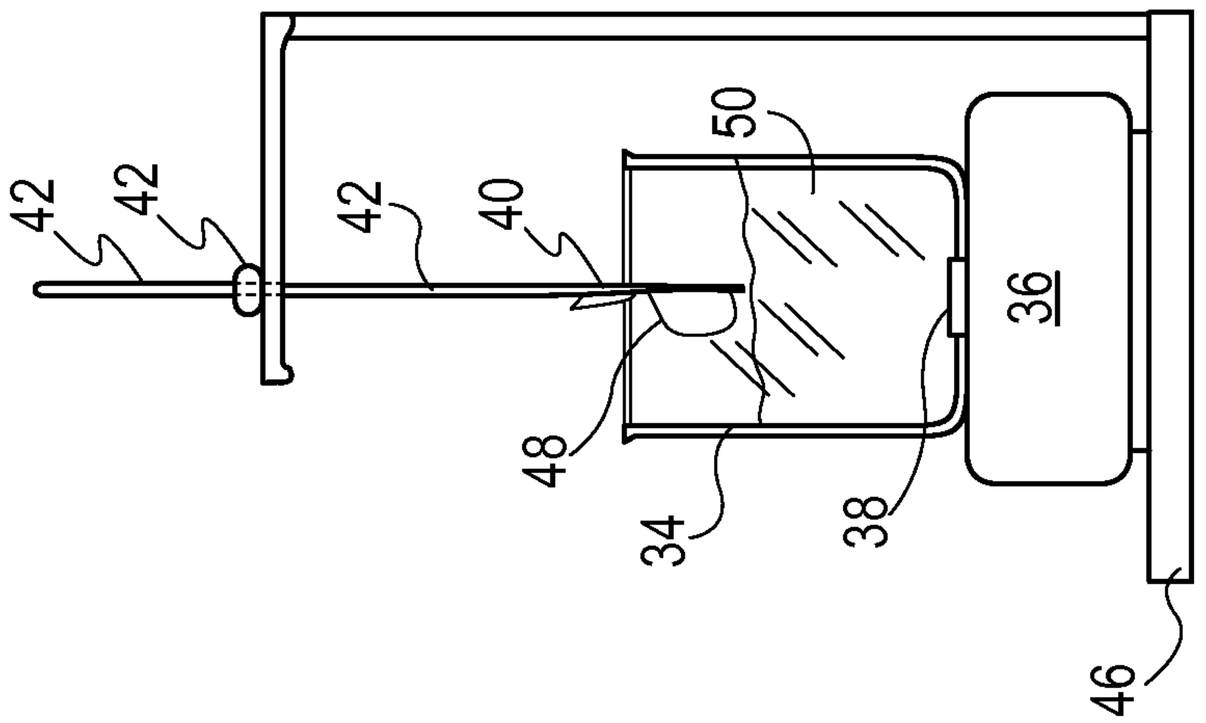

Fig. 4

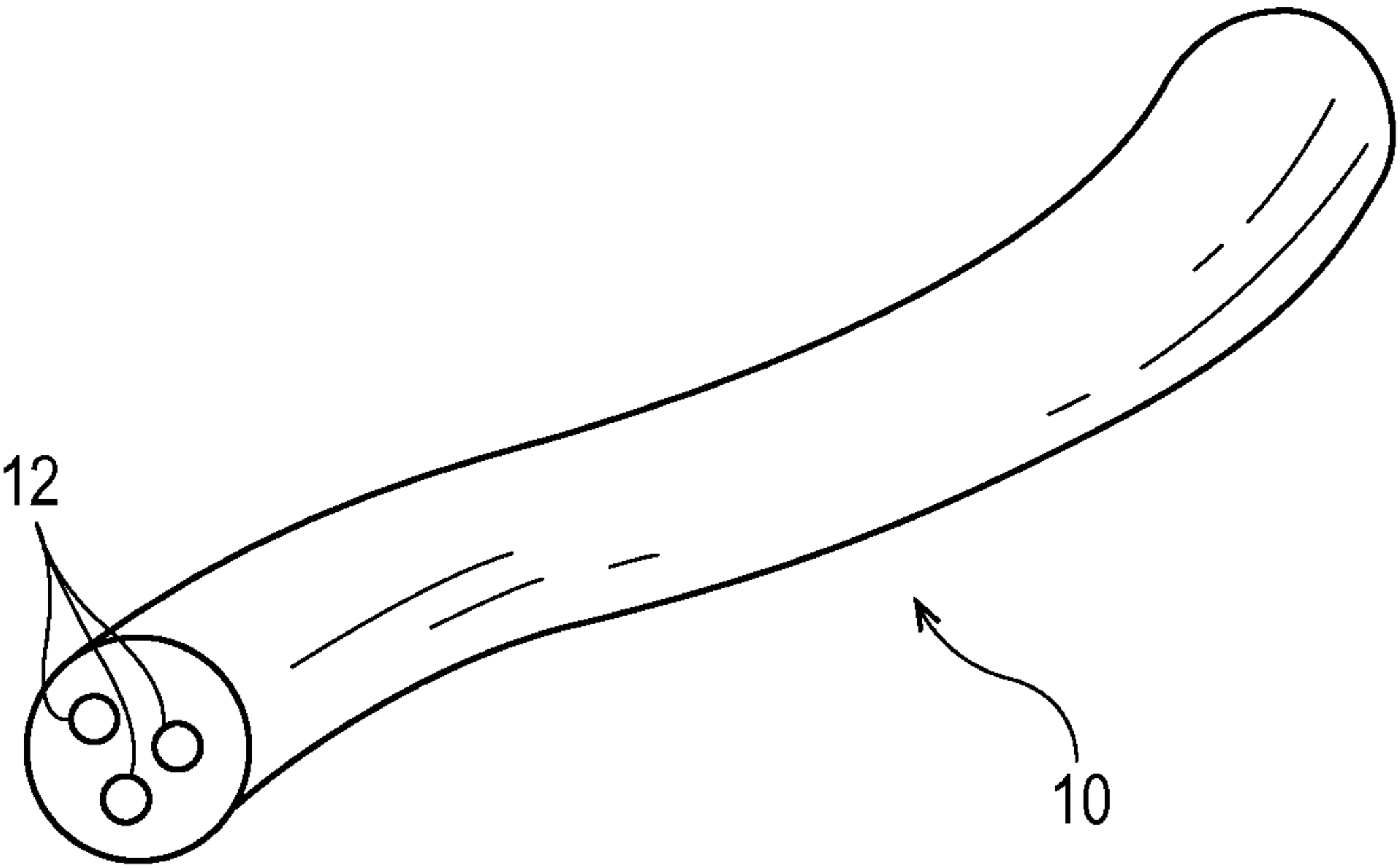

Fig. 1