

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 September 2006 (28.09.2006)

PCT

(10) International Publication Number
WO 2006/100561 A1

(51) International Patent Classification:

B32B 5/24 (2006.01)	A61L 15/42 (2006.01)
B32B 9/04 (2006.01)	A61L 15/44 (2006.01)
B32B 27/40 (2006.01)	A61F 13/02 (2006.01)
A61K 9/70 (2006.01)	A41D 31/02 (2006.01)
A61L 15/28 (2006.01)	A61K 8/02 (2006.01)

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/IB2006/000616

(22) International Filing Date: 20 March 2006 (20.03.2006)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:

MI2005A000467 22 March 2005 (22.03.2005) IT

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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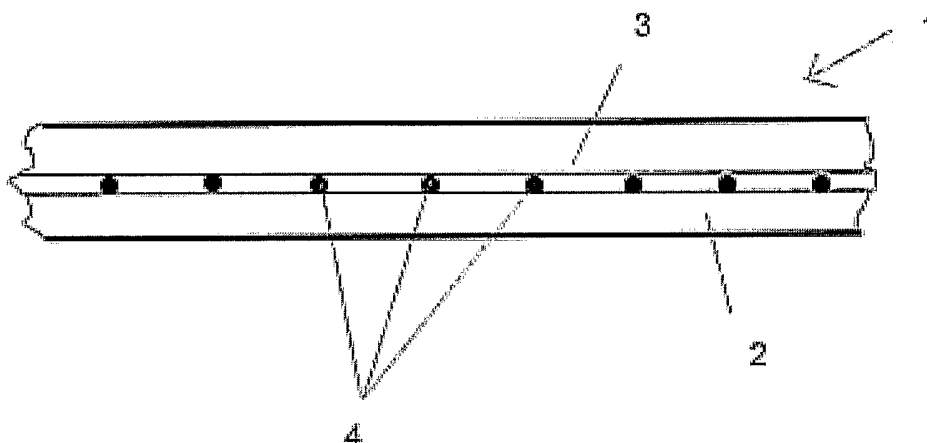
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Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MULTI-PLY TECHNICAL COMPOSITE WHICH IS BREATHABLE AND MOISTURISING, RELEASES ACTIVE CONSTITUENTS AND PROMOTES THEIR ABSORPTION, AND CAN BE USED AS A MEDICAL AID OR TO MAKE CLOTHING OR STRUCTURES THAT COME INTO DIRECT CONTACT WITH HEALTHY OR DISEASED SKIN



(57) Abstract: The invention relates to a multi-ply technical composite, usable in particular for making medical aids, garments and medical articles, comprising at least two layers (2,3), the first of which (2), in contact with the skin, is a cotton fabric (elasticised to a greater or lesser extent) or silk, or fabrics to which chitosan, silver or another antibacterial substance or active constituent is added, and the second, outer layer (3) is constituted by a semipermeable membrane, such as polyurethane between 5 and 80 microns thick, with considerable elasticity in order to ensure the user's comfort. Receptors rechargeable with active constituents are inserted into fabric (2) and protected by the polyurethane membrane.

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**MULTI-PLY TECHNICAL COMPOSITE WHICH IS BREATHABLE
AND MOISTURISING, RELEASES ACTIVE CONSTITUENTS AND
PROMOTES THEIR ABSORPTION, AND CAN BE USED AS A
MEDICAL AID OR TO MAKE CLOTHING OR STRUCTURES THAT
COME INTO DIRECT CONTACT WITH HEALTHY OR DISEASED
SKIN**

This invention relates to a multi-ply technical composite which is breathable and moisturising, releases active constituents and promotes their absorption, and can be used in particular as a medical device or to make clothing or structures that come into direct contact with healthy or diseased
5 skin.

Background to the invention

The textile industry is particularly interested in the needs of the market; demand for materials dedicated to specific functions and, in the case of textile fibres and fabrics, functions which can interact with both healthy and diseased
10 skin, has increased, especially in recent years.

The materials currently used have not proved entirely satisfactory.

Description of the invention

The purpose of the invention is to provide a multi-ply technical composite which guarantees a given degree of breathability, so as to ensure
15 optimum moisturisation of the skin and the ideal conditions for the operation of the active constituents.

Another purpose of the invention is to provide such a multi-ply composite which is usable in association with or incorporates cosmetic or pharmaceutical formulations, aiding their absorption and optimising their
20 properties.

Yet another purpose of this invention is to provide a multi-ply

composite which is flexible, comfortable and possibly antibacterial, and which can be recharged with the active constituent.

These aims are achieved, according to the invention, with the characteristics of the annexed independent claim 1.

5 The invention also relates to medical devices including the multi-ply composites described herein and their use as moisturising agents in dermatological and cosmetic applications.

Advantageous embodiments of the invention are expressed in the dependent claims.

10 **Detailed description of the invention**

Substantially, the multi-ply technical composite according to the invention comprises at least two layers. The first of said layers, which comes into contact with the skin, is a fabric, and the second, external layer consists of a semipermeable membrane.

15 The first layer, which comes into contact with the skin, can be made of cotton (elasticised to a greater or lesser extent), silk, or fabrics to which chitosan, silver or another antibacterial substance or active constituent is added.

20 The second layer, constituted by a membrane of semipermeable material, is preferably made of polyurethane between 5 and 80 microns thick, with considerable elasticity in order to ensure the user's comfort. The membrane could be non-porous, so that the active constituent, if any, does not pass to the outside. In this way, the active constituent is not wasted, and as it does not reach the outer surface, it does not soil bedclothes, clothing or other
25 dressings.

Said membrane is able to breathe by osmosis, and consequently does not form an occlusive dressing.

The annexed figure shows a schematic partial cross-section of a two-ply

technical composite according to the invention, indicated globally as no. 1 and comprising a first inner layer 2 made of fabric, such as cotton, silk or another fibre, and a second outer layer 3 made of polyurethane, which are bonded firmly to one another, preferably by a hot-pressing process, using microdots of
5 anallergic glue (4) specifically designed for this purpose, with a diameter which can be calculated at between 0.15 mm and 0.7 mm, placed at regular intervals, so that 60 to 180 dots per square centimetre can be counted. The regular spacing of the glue dots provides a suitable ratio between the glued surface and the free surface.

10 This structure optimises the inclusion of rechargeable receptors containing moisturising or more specifically therapeutic active constituents such as cyclodextrins, microsponges, liposomes and nanoparticles.

If applied to the skin (layer of cotton and/or other material in contact with the epidermis, and polyurethane membrane on the outside), depending on
15 the objective parameters of intactness of the stratum corneum and the skin barrier, the multi-ply technical composite according to the invention improves the barrier and moisturising function of the skin; in other words, it acts as a moisturising substance. These properties can be demonstrated with the use of non-invasive methods such as transepidermal water loss (TEWL) and
20 corneometry.

If used after the application of moisturising substances and/or active constituents, it promotes their activity and penetration.

The best results have been obtained with a composite of the type described above; in particular, a study has been conducted to evaluate the
25 significant, innovative effects of the material on some skin physiology parameters.

The study was conducted on 15 subjects. The multi-ply composite was applied "as is" to the skin at two different sites: the volar surface of the

forearm and the front abdominal region. The composite was left in position for eight consecutive hours to simulate the use of the product by consumers instead of underwear or pyjamas. Eight hours after the application, a number of instrumental tests were performed to investigate the changes which had
5 taken place in the skin. In particular, the transepidermal water loss (TEWL) was measured, and the fluid content of the stratum corneum was measured by corneometry. The TEWL measurement measures the quantity of water vapour that evaporates on the surface of a given substrate, while corneometry is a technique based on detection of electrical capacitance which varies with the
10 water content of a given body. All these tests were performed using a pure cotton fabric (placebo), applied by the same procedure, as control, and skin on which no product was positioned as negative control. The results demonstrated that after 8 hours' application of the test product to the skin surface, normal skin breathing through the membrane was maintained, with TEWL indexes
15 comparable to those of cotton, associated with a (statistically significant) increased water content of the stratum corneum compared with cotton or the control skin.

This finding confirms the unique breathability of this product and its ability to increase skin moisturisation. Other membranes are unable to
20 increase moisturisation when they are breathable. In a later study, which repeated the same test procedure, a moisturising cream was applied at the interface between product and skin. The result was even more marked (including statistically); high breathability was maintained (TEWL through the product), and associated with an excellent skin moisturising effect. This
25 supports the use of the product in association with moisturising formulations in the treatment of various skin conditions characterised by dryness of the skin, such as diffuse xerosis, atopic dermatitis, psoriasis, etc.. In addition to the use of the product in association with cosmetic or parapharmaceutical

formulations, materials used in the pharmaceutical and cosmetic industry for the controlled release of active constituents, such as cyclodextrins, microsponges, liposomes, nanoparticles and biopeptides, can be incorporated in the finished product in order to increase the efficacy of said formulations.

5 It is known in skin pharmacology that the release and transcutaneous penetration of many active constituents takes place under optimum skin moisturising conditions; when the skin is dehydrated, these technologies often present problems with the linearity of controlled release, and therefore cannot be exploited to the full for therapeutic purposes. Some practical uses of the
10 multi-ply composite according to the invention containing said slow-release particles (cyclodextrins, microspheres, liposomes etc.) could be their combination with active substances to treat blemishes caused by cellulite, topical anti-inflammatory substances (cortisone, NSAIDs, plant protection products, glycyrrhetic acid, vitamins and antioxidant substances), or the
15 treatment of desquamative dermatitis (urea, vitamin D derivatives, retinoids etc.).

Moreover, antiseptic and antibacterial active constituents of various kinds such as chlorhexidine, triclosan, undecylenic acid, climbazole and other imidazole derivatives can be carried in controlled-release systems associated
20 with the multi-ply composite and used for the treatment of impetiginous dermatitis, yeast infections and fungi in general, etc. The inclusion in the multi-ply system of silver (in various forms) also allows a preventive antimicrobial action to be performed to prevent and control bacterial and/or fungal infections in various disorders such as atopic dermatitis, various kinds
25 of ulcerative lesions of the lower limbs, skin complications associated with some metabolic and inflammatory disorders such as diabetes, connective tissue disease and vascular diseases in general.

In particular it could be used in garments dedicated to the disorder or

the part of the body to be treated, such as t-shirts, with or without sleeves, trousers, pyjamas, sheaths, gloves, caps, face masks, dressings, stockings, kneepads, underpants etc. for the treatment of various skin and other diseases, such as contact dermatitis, psoriasis, sprains and dislocations, joint problems, etc..

To sum up, the multi-ply technical composite according to the invention performs a breathing action by osmosis which allows sweat to be transported to the outside of the polyurethane membrane, thus preventing maceration, while it prolongs and optimises the action of any active or moisturising constituents (occlusive-like effect) so that the active constituent is not released to the exterior, in such a way that the outer surface of the membrane is not affected, and clothes, sheets, dressings and the like are not soiled, so that even patients with considerable problems do not need to interrupt their normal activities.

As already stated, this multi-ply composite can be used to make t-shirts, with or without sleeves, trousers, pyjamas, sheaths, gloves, caps, face masks and dressings.

A third outer layer with an aesthetic or finishing function can be bonded to this multi-ply technical fabric, again with glue dots or netting, using a hot-pressing process.

CLAIMS

1. Multi-ply technical composite, particularly effective for medical aids and garments, comprising at least two layers, the first of which (2), in contact
5 with the skin, is a fabric, while the second outer layer (3) is constituted by a semipermeable membrane.
2. Multi-ply composite as claimed in claim 1, characterised in that said first layer of fabric (2) in contact with the skin is cotton or silk.
3. Multi-ply composite as claimed in claim 2, characterised in that said
10 cotton or other fabric is elasticated.
4. Multi-ply composite as claimed in any of the preceding claims, characterised in that chitosan, silver (in various forms) or antibacterials are added to said fabric (2).
5. Multi-ply composite as claimed in any of the preceding claims,
15 characterised in that said fabric (2) incorporates receptors chosen from among cyclodextrins, nanoparticles, microsponges and biopeptides.
6. Multi-ply composite as claimed in any of the preceding claims, characterised in that said semipermeable membrane forming the second, outer layer (3) is made of elastic polyurethane.
- 20 7. Multi-ply composite as claimed in any of the preceding claims, characterised in that the bonding of said semipermeable membrane forming the second, outer layer (3) to fabric layer (2) aids concentration and fixing of the receptors (cyclodextrins, nanoparticles, microsponges and biopeptides).
8. Multi-ply composite as claimed in claim 6, wherein said polyurethane
25 membrane is able to breathe by osmosis, and does not create an occlusive effect.
9. Multi-ply composite as claimed in claim 6, wherein said polyurethane membrane is able to breathe by osmosis, thus promoting moisturisation of the

skin and restoring the skin barrier.

10. Multi-ply composite as claimed in claims 5 and 6, wherein said polyurethane membrane is able to retain in the interior (in contact with the skin) the active constituent, either free or bonded to receptors, and does not
5 allow it to pass or be dispersed to the exterior.

11. Multi-ply composite as claimed in claim 5, wherein said polyurethane membrane has a thickness of between 5 and 80 microns.

12. Multi-ply composite as claimed in any of the preceding claims, wherein said layers (2, 3) are bonded firmly together with a hot-pressing process, using
10 microdots of anallergic glue (4) with a diameter of between 0.15 mm and 0.7 mm.

13. Multi-ply composite as claimed in any of the preceding claims, characterised in that it includes receptors chosen from among cyclodextrins, microsponges, liposomes, nanoparticles and biopeptides, which can be
15 recharged with moisturising or therapeutic active constituents.

14. Multi-ply composite as claimed in claim 13, used in combination with active substances in the treatment of blemishes caused by cellulite, topical anti-inflammatory substances, cortisone, NSAIDs, plant protection products, glycyrrhetic acid, vitamins or antioxidants, or in desquamative dermatitis,
20 such as urea, vitamin D derivatives and retinoids.

15. Composite as claimed in any of the preceding claims, characterised in that it includes antiseptic and antibacterial active constituents chosen from among chlorhexidine, triclosan, undecylenic acid, climbazole and imidazole derivatives used for the treatment of impetiginous dermatitis, yeast infections
25 and fungi in general.

16. Composite as claimed in any of the preceding claims, characterised in that it includes at least an additional, third outer layer with an aesthetic or finishing function.

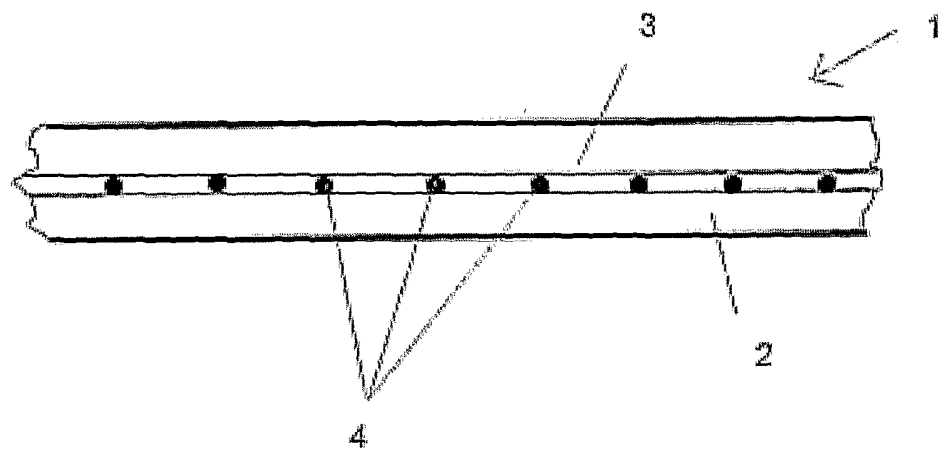
17. Multi-ply composite as claimed in claim 16, wherein said additional outer layer is bonded by glue dots or netting using a hot-pressing process.

18. Composite as claimed in any of the preceding claims, used to make t-shirts, with or without sleeves, trousers, pyjamas, sheaths, gloves, caps, face
5 masks, dressings, stockings, kneepads, underpants and garments in general.

19. Medical aids or garments made with a multi-ply technical composite as claimed in any of the preceding claims.

20. Use of the composites claimed in claims 1-18 as skin moisturising agents.

FIGURE



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/000616

A. CLASSIFICATION OF SUBJECT MATTER INV. B32B5/24 B32B9/04 B32B27/40 A61K9/70 A61L15/28 A61L15/42 A61L15/44 ADD. A61F13/02 A41D31/02 A61K8/02 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61K A61L B32B A61F A41D Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex. </div>		
<div style="display: flex;"> <div style="flex: 1;"> <p>* Special categories of cited documents:</p> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the international filing date</p> <p>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="flex: 1;"> <p>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>*G* document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search		Date of mailing of the international search report
27 July 2006		03/08/2006
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Lindner, T

INTERNATIONAL SEARCH REPORT

International application No
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