



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61L 15/12, 15/14	A1	(11) International Publication Number: WO 94/03211 (43) International Publication Date: 17 February 1994 (17.02.94)
(21) International Application Number: PCT/GB93/01670 (22) International Filing Date: 6 August 1993 (06.08.93) (30) Priority data: 9216775.8 7 August 1992 (07.08.92) GB (71) Applicant (for ES only): USM ESPANA S.L. [ES/ES]; Apartado 3174, Berenguer de Palou, 64, E-08027 Barcelona (ES). (71) Applicant (for all designated States except ES US): BRITISH UNITED SHOE MACHINERY LIMITED [GB/GB]; P.O. Box 88, Ross Walk, Belgrave, Leicester LE4 5BX (GB). (72) Inventor; and (75) Inventor/Applicant (for US only) : ARNOLD, Brian [GB/GB]; 43 Orchard Way, Syston, Leicestershire LE4 5BX (GB).		(74) Agent: ATKINSON, Eric; Patents & Legal Department, USM Texon Limited, P.O. Box 88, Ross Walk, Belgrave, Leicester LE4 5BX (GB). (81) Designated States: AU, CA, JP, NO, NZ, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: ORTHOPAEDIC SPLINTING/CASTING MATERIAL		
(57) Abstract <p>An orthopaedic splinting/casting material comprises a high molecular weight polyester in combination with a cellulosic filler, the material is mouldable at a temperature in the range of 55 to 70 °C and has a self-adherent characteristic at such temperature, its weight is in the range 0.75 to 4.0 kg/m², its density in the range 900 to 1200 kg/m³, and its modulus, at ambient temperature, not less than 350 mPa. Preferably the polyester is a polyhexamethylene adipate or a polyepsilon-caprolactone. The cellulosic filler may be one or a combination of ground almond shell, ground olive stones and wood flour. Preferably the polyester is in powder form, in which case the polyester and the filler are both generally of the same or closely similar grain size distribution. If desired a fabric layer, e.g. a lightweight polyester fabric, may be incorporated at or adjacent at least one surface of the polyester/filler material.</p>		

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ORTHOPAEDIC SPLINTING/CASTING MATERIALTECHNICAL FIELD

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This invention is concerned with orthopaedic splinting/casting materials.

BACKGROUND ART

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There are described in GB-A-1 366 091 various formable orthopaedic cast materials in the form of a bandage, web, film, tape or sheet for use in the treatment of both human and animal bodies, in particular in the case of broken limbs and sprains. In the case of each of the various materials there described it is proposed to use high molecular weight poly-epsilon-caprolactone, either as a component of a blend or as a sole polymeric constituent. Poly-epsilon-caprolactone had the advantage of being easily and rapidly applicable to the affected body part when heated to a moulding temperature, while forming a rigid, non-irritating, strong, durable, water-resistant, close-fitting splint or cast when at temperatures below the softening temperature, which splint or cast was nevertheless easily removable when no longer required without risk of injury or irritation to the patient and indeed without serious damage to the material itself, which could therefore be sterilised and re-used, if desired. Because the splint or cast could be custom-made from sheet or the like, furthermore, it was not necessary to stock different sizes or styles of splint or cast. Moreover, splints or casts made from poly-epsilon-caprolactone are relatively light in weight and do not have the disadvantages of being bulky, as was the case with previously used plaster of Paris, for example. Moreover, the softening

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1 temperature of poly-epsilon-caprolactone is in the range
55 to 70°C, which, especially bearing in mind the low
thermal conductivity of the material, would not cause
discomfort to the patient whose body part is brought into
5 contact with the thus softened material.

Problems have, however, been perceived in the
use of poly-epsilon-caprolactone and various proposals
have been made for modifying it, and in particular for
blending it with other polymeric materials, in order to
10 achieve physical characteristics which are considered to
be desired: see e.g. US-A-4,144,223, GB-A-2 015 004 and
WO 83/02898.

It is of course well known that the physical
characteristics of a polymer can be significantly varied
15 by the use of fillers, which also of course in general
render the cost of the material cheaper. Thus, in
GB-A-1 366 091 it is proposed that up to 25% by weight
filler can be used. Moreover, the proposed fillers in
this case include magnesium or calcium carbonate, finely
20 divided silica, clay, asbestos and alpha cellulose, the
filler particles in each case being in a size range of 3
to 4 microns. In other proposals made, fillers having a
particle size up to 50 microns have been proposed, again
however of the same filler types as referred to in
25 GB-A-1 366 091.

It is also known to provide a material for use
in reinforcing/stiffening shoes, which material comprises
a polyester having a molecular weight of not less than
10,000 and a viscosity measured at 100°C of at least
30 Pa.s in combination with a filler, said material being
mouldable at a temperature in the range 55 to 70°C,
having a weight in the range 0.75 to 1.25 kg/m², a
density in the range 900 to 1200 kg/m³, and a modulus, at
ambient temperature, in the order of 350 to 700 mPa. One
35 such material is described in our co-pending

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1 EP-A-0 448 294, which material comprises a
polyhexamethylene adipate of the type described, along
with its manner of manufacture, in EP-A-0 448 079. In
addition, there are described in EP-A-0 349 140 and
5 EP-A-0 183 912 respectively shoe reinforcing/stiffening
materials comprising a polycaprolactone.

In the last mentioned specification it is
proposed to use a filler which is made wholly of or at
least a surface of which is coated with a synthetic
10 material, one preferred embodiment comprising hard PVC.
In EP-A-0 349 140, on the other hand, a filler is
proposed in the form of pulverised fuel ash, while in
EP-A-0 448 294, in addition to the two fillers already
referred to, a proposal is made to utilise almond shell
15 grain, olive stone grain or wood flour.

In contrast with the relatively low grain size
distribution of the materials disclosed in
GB-A-1 366 091, the grain size distribution in each of
the three EP Specifications referred to is substantially
20 greater, being in the order of 50 to 500, preferably 100
to 400 (in the case of 0 183 912), 350 microns (in the
case of 0 349 140), and up to 600 microns (in the case of
0 448 294). Thus, in the case of the reinforcing/
stiffening materials for shoes, a substantially higher
25 grain size distribution of the filler is encountered than
in the previous cases relating to splinting/casting
materials.

In using a splinting or casting material based
upon poly-epsilon-caprolactone, or indeed any other
30 splinting or casting material, it is highly desirable,
especially in the case of the smaller body parts, for the
moulding of the material to follow closely the shape of
the body part to which the splint or cast is to be
applied. In addition, it is highly desirable that the
35 "feel" of the contacting surface of the material is

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1 comfortable to the patient. In the case of larger limbs
it may be that a suitable sheet material can be
interposed between the casting or splinting material on
the one hand and the skin on the other, but, in
5 particular in the case of smaller body parts, such an
interlining would be detrimental to the accuracy of the
moulding to the shape of the body part in question. It
is thus very desirable for the surface of the material
itself to have the desired "feel".

10 A further feature which has been found
desirable, and which is closely related to the
comfortable "feel" referred to above, is to ensure that
sufficient ventilation is provided to the region of the
skin encased by the cast or splint material. In e.g.
15 US-A-4,240,415, therefore, it is proposed to perforate
the material over the whole of its area.

OBJECT OF THE INVENTION

20 It is thus an object of the present invention
to provide an improved orthopaedic splinting/casting
material which is moisture-permeable and which has a
comfortable "feel" when applied to a body part.

SUMMARY OF THE INVENTION

25 It has now been established that, surprisingly,
the shoe reinforcing/stiffening materials are in certain
circumstances, and with selected fillers, appropriate in
30 resolving the object of the present invention. More
particularly, the solution in accordance with the present
invention resides in the use, as an orthopaedic splinting
or casting material, of a material in sheet or strip form
comprising not less than 50% by weight of a polyester
35 having a molecular weight of not less than 10,000 and a

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1 viscosity measured at 100°C of at least 30 Pa.s, and up
to 50% by weight of a cellulosic filler, said material
being mouldable at a temperature in the range 55 to 70°C,
being self-adherent at such moulding temperature, and
5 having

- a weight in the range 0.75 to 4.0 kg/m²,
- a density in the range 900 to 1200 kg/m³, and
- a modulus, at ambient temperature, of not less than
350 mPa.

10 It has been found that the use of such a material affords
comfort to the wearer in terms both of the surface "feel"
of the material and also by reason of the material being
moisture-permeable. (Tests have shown that vapour
transmission rates through the material are in the order
15 of not less than 300 mg/m²/hour.) The reason for the
moisture-permeability is not wholly understood, but it is
believed that the presence of relatively large particles
of cellulosic filler, constituting up to 50% of the total
weight of the polyester/filler composition, allows paths
20 through the thickness of the material by the
juxtaposition of moisture-absorbent filler particles.
Moreover, it may be presumed that, based on the
difference in density between the constituent parts and
the overall density of the material, the material is in
25 fact also microporous.

The stiffness of the material, which is of
course a function of the thickness and modulus, depends
largely upon the requirements for the particular body
part to be treated. Thus, in the case of, say, a
30 fractured limb, a heavy gauge material will be required
in order totally to immobilise the limb in question. In
the case of a moderate sprain, on the other hand, a much
less thick (and thus a much less stiff) material will be
adequate. It is likely, therefore, that materials having
35 a thickness in the range 1 to 4mm will be adequate for

1 most purposes in accordance with the invention.

Suitable polyesters for use in a material as referred to above are preferably aliphatic polyesters, e.g. poly-epsilon-caprolactone (which is a polymer formed of a cyclic ester) and polyhexamethylene adipate of a type having high molecular weight, as disclosed in EP-A-0 448 079. Moreover, preferably the polyester has a molecular weight of at least 30,000 and a viscosity measured at 100°C of at least 600 Pa.s.

10 Preferably the material comprises not less than 55% by weight polyester; more preferably the polyester:filler ratio is in the order of 60:40.

Preferably the material incorporates a fabric layer at or adjacent at least one surface. The fabric layer is preferably a non-woven synthetic material, e.g. viscose or polyester, having a melt temperature higher than that of the polyester, in which case there is little or no tendency for the non-woven layer to soften when the polyester/filler composition is softened. Preferably, furthermore, the or each fabric layer has a weight not exceeding about 0.025 kg/m². When the material is in use, and especially when pressure is applied to the material in its softened state, sufficient of the polyester/filler material passes through the fabric layer to provide an adhesive surface, but the fabric layer does not become wholly embedded in the polyester/filler composition. Thus, by the provision of such a layer or layers, when the material has been heated to soften it, the effect of the layer(s) is to render the hot material more readily capable of being handled comfortably not only from the point of view of the heat in the composition, but also in reducing the tendency of the material to stick to the hands of the person handling it. Similarly, the fabric layer has the same effect in relation to the skin of the patient. Moreover, by

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1 providing what is essentially a non-flat surface, by
arranging the fabric layer(s) at or adjacent the surface
of the material, an air gap is created between the
material and the skin of the patient, and this air gap is
5 believed to contribute to the comfortable "feel" of the
material when in use. A further advantage of the use of
a fabric layer in this manner is that it can be utilised
to alter the tensile properties of the finished product;
where, for example a non-woven layer is used which has
10 been produced by carding and then bonding fibres, it
significantly restrains elongation of the finished
product in the "machine" direction, i.e. the direction in
which the fibres are laid. In the case of e.g. spun-
bonded or hydro-entangled non-woven fabrics, on the other
15 hand, the tendency of the composition to stretch when
softened can be restrained in all directions.

The cellulosic filler is preferably selected
from one or a combination of the following:

- 20 - ground almond shell having a grain size distribution
of 150 to 400 microns,
- ground olive stones having a grain size distribution
of 150 to 400 microns, and
- wood flour having a grain size distribution of up to
a maximum of 600 microns.

25 It will of course be appreciated by the
selection of different fillers, the stiffness of the
finished product can be varied. The selection of a
particular cellulosic filler to be used will be
determined largely according to the desired weight and
30 stiffness of the finished product.

One significant advantage of the material
referred to above has been found to be that it is
substantially transparent to X-rays. Thus it is possible,
while a splint made of said material remains in situ for
35 the limb to be X-rayed without any significant increase

1 in the level of radiation.

5 A preferred manner of manufacturing the material for use as referred to above is by a powder deposition process in which the polyester in powder form is first mixed with the filler; it should of course be understood that the grain size distribution of the polyester powder should be the same as or closely similar to that of the filler in order to ensure proper mixing and to prevent separating out during dispensing of the powder. The thus mixed powder is then deposited in a measured layer on a band of non-woven fabric which passes beneath the dispensing hopper and is supported on a suitable belt and thereafter preferably a second layer of non-woven fabric is laid over the thus deposited layer and the "sandwich" is passed through a double-band press, e.g. of the type described in EP-A-0 322 145. This press serves by heating and subsequent cooling to fuse and consolidate the powder into a continuous material; if desired, a pre-heating step may be included prior to the second non-woven layer being introduced, this pre-heating step serving to cause an initial fusion of the powder materials. After the consolidated material has left the belts of the press, and while it is in a still mouldable state, it is passed between rollers by which the final thickness (gauge) of the material is determined. Thereafter the material is either formed into rolls or cut into sheets and stacked. In a different method of production, still utilising a powder deposition process, the press may be replaced by an oven, in which case the second non-woven layer may be dispensed with, while in yet another method of production two plies of material are used, one comprising two layers of a non-woven fabric with a polyester layer therebetween, as referred to above, and the other comprising a layer of polyester having a layer of non-woven fabric on one side only

1 thereof, the two plies being placed in face-to-face
contact, with the fabric surface of the second ply
exposed, and being passed through a double-band press as
aforesaid. In such a material, it will be appreciated,
5 one layer of non-woven fabric is thus located between the
two polyester layers. Moreover, it will also be
appreciated, other material than a polyester non-woven
fabric may be selected for this intermediate layer
according to any particular characteristic desired for
10 the material as a whole, bearing in mind of course the
overall need to retain sufficient flexibility to ensure
that the material will nevertheless be mouldable to the
shape of the limb to be supported thereby.

 In using the material, firstly it is necessary
15 to soften it by the application of heat. In one
preferred use this is effected by immersing the material
in a bath of hot water at, say, 70°C; alternatively, if
available an oven may be used for the same purpose.
Where the material is in sheet form it will normally have
20 been cut to an appropriate size and shape prior to
immersion or other form of heating, while if in the form
of a strip, e.g. a bandage, it will have been cut to
length prior to immersion or other heating. When the
material has reached the desired temperature it is then
25 removed from the heat source and applied to the body part
of the patient. At this stage although the substance of
the material has been heated to a relatively high
temperature, in terms of what is tolerable by the
patient, because of the relatively low thermal
30 conductivity of the material, it is unlikely that
significant discomfort will be caused to the patient by
bringing the material into skin contact. Depending upon
the particular composition of the material, the material
will remain mouldable for a known period, likely to be
35 between one minute and, say, five minutes, thus giving a

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1 "window" for the moulding of the material to the affected
body part of the patient. Moreover, depending upon the
degree to which the material is heated, and also
depending upon to what extent the temperature reached
5 approximates to the crystalline temperature of the
material, the material will be self-adherent for at least
the initial part of the "window", so that it is possible
for the person treating the patient to mould the material
to the desired shape and to cause it to adhere to itself,
10 as least as a temporary fixing. In the case of splints
for minor sprains, the fixing by self-adherence may be
adequate; in the case of casts for fractured limbs, on
the other hand, it may be desirable to provide further
straps, which may be of the same material, applied
15 subsequently, e.g. by heating locally with a heat gun.

When it is desired to remove the splint or
cast, moreover, this may be achieved by again heating to
soften the material and then to unwrap it.

20 MODES FOR CARRYING OUT THE INVENTION

The manufacture of various materials suitable
for use in carrying out the invention will now be further
described with reference to the following specific
25 examples.

EXAMPLE I

A polyhexamethylene adipate in powder form
having a molecular weight calculated at approximately
30 30,000, a viscosity of approximately 800 Pa.s at 100°C
and a particle size range of 0 to 600 microns, which is
available from Bostik Limited under the designation
Bostik HM5189AE ("Bostik" is a registered trade mark) was
mixed in a ratio of 60:40 parts by weight with a
35 cellulosic filler in the form of ground almond shell

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1 having a particle size range of 150 to 400 microns. The
mixture was then fed to a hopper through which it was
dispensed at a uniform rate onto a lightweight non-woven
polyester fabric having weight of 0.18 kg/m² supported by
5 the lower belt of a double-band press by which the fabric
was advanced beneath the hopper at a uniform rate.
"Downstream" of the hopper was arranged an infrared
heater by which an initial fusion of the mixture took
place, whereafter the thus initially fused composition
10 was covered with a second, similar, non-woven polyester
fabric and the laminate was then passed between the upper
and lower belts of the double-band press, in which heat
was first applied by platens arranged at opposite sides
of the belts and heated to a surface temperature of
15 150°C, whereafter, for a short period, the bands were
moved over cooling platens, also arranged at opposite
sides of the press, maintained at a temperature of 5°C.
Moreover, the gap between the belts progressively tapered
towards the outlet end in order thus to consolidate the
20 material to some extent. For consolidating the material
further, to a pre-determined gauge, moreover, the
material was then passed between two consolidating
rollers having also a surface temperature maintained at
or about 5°C. The material could thereafter either be
25 stored in roll form (the material still being
sufficiently mouldable for this purpose) or be cut into
sheets and stacked.

The material thus made had the following
characteristics:

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Thickness	1.09mm
Weight	1.020 kg/m ²
Density	940 kg/m ³
Modulus (at ambient temperature)	373 MPa.

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1 This material was capable of being used either
in strip form, e.g. as a bandage, or in sheet form.
Because of its relatively low gauge, it is unlikely that
such material in sheet form would be used other than for
5 splinting or perhaps for casting in the case of
relatively small body parts.

EXAMPLE II

10 The same polyhexamethylene adipate and filler
as used in Example I was also used in this Example in the
same ratio, but in this case the characteristics of the
finished material were as follows:

	Thickness	2.50mm
15	Weight	2.855 kg/m ²
	Density	1.14 kg/m ³
	Modulus	536 MPa

20 In this case it is unlikely, because of the
thickness of the material, that it would be used other
than in sheet form, and the material has been found to be
useful especially as a casting material. The advantages
of this material, as opposed to e.g. plaster of Paris,
are essentially ease of application and light weight.

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EXAMPLE III

30 In this Example the ground almond shell filler
was replaced by ground olive stone filler of the same
particle size range, all the other parameters for the
mixture remaining the same. It was found in practice
that this material did not significantly differ in
physical characteristics from the material of Example I.
From this it is concluded that the olive stone filler
acts in by and large the same manner with the same effect
35 as the almond shell filler over the whole range of

1 thicknesses of the material.

EXAMPLE IV

5 In this case the material was made in a laboratory using a conventional platen press with shims between the platens to determine the thickness to which the material was consolidated. The material in this case, moreover, was a powder mixture in the following ratio by weight:

10	Polycaprolactone (CAPA 656)	60
	Ground almond Shell having a particle size of 300-600 microns	20
15	Wood Flour have a particle size of 0-400 microns	20

The above mixture was dispersed on release paper and, after dispersion, a further release paper was placed over the mixture and the "sandwich" was placed in the platen press and consolidated at a temperature of 120°C. The finished product had the following physical features:

25	Thickness	1.43mm
	Weight	1.6 kg/m ²
	Density	1120 kg/m ³
	Modulus	860 MPa.

30 It will thus be appreciated that in this case a much stiffer material was achieved, which nevertheless could be handled in generally the same manner as the other Examples when softened to a temperature between 55 and 70°C.

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1 EXAMPLE V

 In this case a two-ply material is produced. Each ply comprises a layer of a polyhexamethylene adipate in powder form having a molecular weight, viscosity and particle size in a similar range to that of the polyhexamethylene adipate of Example I, but in this case being identified by the designation Bostik HM5512AE. In the case of each layer, furthermore, the polyester was mixed with a cellulosic filler in the form of ground almond shell having a particle size range of 150 to 400 microns. The first ply of said material was produced by depositing a metered polyester:filler layer on a layer of non-woven polyester fabric and thereafter a further layer of the same fabric was placed thereover. The second ply was produced by depositing a metered layer of the polyester:filler mixture on a layer of polyester non-woven fabric. The two plies were then superposed with the fabric surface of the second ply exposed; that is to say with one of the fabric layers of the first ply intermediate the two polyester layers. The "sandwich" was then passed through a double-band press and the process was completed generally in the same manner as described in Example I.

25 The finished material had the following characteristics:

	Thickness (average)	2.64mm
	Weight	3125 kg/m ²
30	Density	1180 kg/m ³
	Modulus (at ambient temperature)	706 MPa (width) 770 MPa (length).

The moisture vapour permeability was 385mg/m²/hr.

1 The material exhibited good handling qualities and
has been found suitable for use as a casting material.

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1 Claims:

1. The use, as an orthopaedic splinting or casting material, of a material in sheet or strip form comprising
5 not less than 50% by weight of a polyester having a molecular weight of not less than 10,000 and a viscosity measured at 100°C of at least 30 Pa.s, and
 up to 50% by weight of a cellulosic filler,
said material being:

- 10 - mouldable at a temperature in the range 55 to 70°C and being self-adherent at such moulding temperature,
 - having a weight in the range 0.75 to 4.0 kg/m²,
 - having a density in the range 900 to 1200 kg/m³, and
15 - having a modulus, at ambient temperature, of not less than 350 mPa.

2. The use of a material as set out in Claim 1 wherein the polyester is an aliphatic polyester.

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3. The use of a material as set out in Claim 1 wherein the polyester is a polymer formed of a cyclic ester.

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4. The use of a material as set out in Claim 1 wherein the polyester is a poly-epsilon-caprolactone.

5. The use of a material as set out in Claim 1 wherein the polyester is a polyhexamethylene adipate.

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6. The use of a material as set out in Claim 1 wherein the polyester has a molecular weight of at least 30,000 and a viscosity measured at 100°C of at least 600 Pa.s.

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1 7. The use of a material as set out in Claim 1
wherein the polyester:filler ratio is in the order of
60:40.

5 8. The use of a material as set out in Claim 1
incorporating a fabric layer at or adjacent at least one
surface.

10 9. The use of a material as set out in Claim 8
wherein the fabric of said at least one layer is a non-
woven fabric of synthetic material having a melt
temperature higher than that of the polyester.

15 10. The use of a material as set out in Claim 1
wherein the filler is selected from one or a combination
of the following:

- ground almond shell having a grain size distribution
of 150 to 400 microns,
- ground olive stones having a grain size distribution
20 of 150 to 400 microns, and
- wood flour having a grain size distribution of up to
a maximum of 600 microns.

25 11. An orthopaedic splinting or casting material in
sheet or strip form comprising

not less than 50% by weight of a polyester having a
molecular weight of not less than 10,000 and a viscosity
measured at 100°C of at least 30 Pa.s, and

30 up to 50% by weight of a cellulosic filler,
said material being mouldable at a temperature in the
range 55 to 70°C, being self-adherent at such moulding
temperature and having

- a weight in the range 0.75 to 4.0 kg/m², preferably
1.25 to 3.75 kg/m², more preferably 2.0 to 3.5
35 kg/m²,

- 1 - a density in the range 900 to 1200 kg/m³, and
- a modulus, at ambient temperature, of not less than
350 MPa.

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INTERNATIONAL SEARCH REPORT

Int. .onal Application No

PCT/GB 93/01670

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 5 A61L15/12 A61L15/14

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)
 IPC 5 A61L

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR,A,2 516 091 (DAICEL CHEMICAL INDUSTRIES) 13 May 1983 see page 4, line 17 - line 26 see page 8, line 1 - line 29 see claims; examples ---	1-3,5-8, 11
X	FR,A,2 332 001 (HEXCEL CORPORATION) 17 June 1977 see page 8, line 3 - line 10 see page 13, line 1 - line 17 see claims ---	1-4
A	EP,A,0 305 842 (BAYER AG) 8 March 1989 see column 5, line 6 ---	1,10
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Date of the actual completion of the international search

29 October 1993

Date of mailing of the international search report

15. 11. 93

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,
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COUSINS-VAN STEEN, G

INTERNATIONAL SEARCH REPORT

Int. .onal Application No

PCT/GB 93/01670

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