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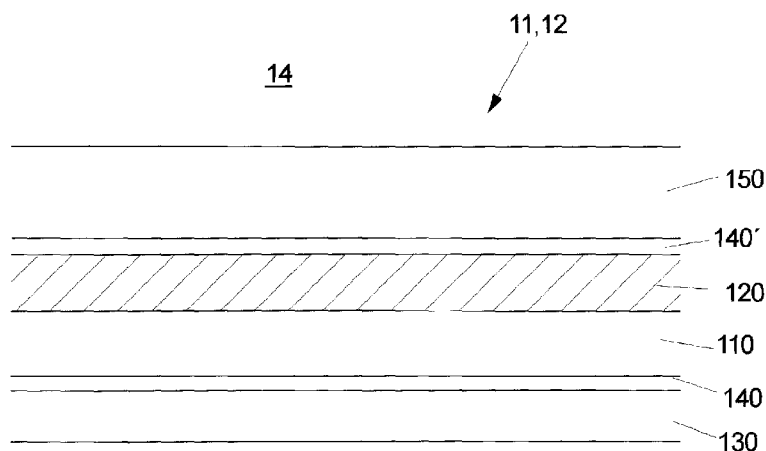
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(54) Title: CONTAINER FOR RECEIVING A NUTRIENT OR PHARMACEUTICAL LIQUID AND METHOD FOR FABRICATING A CONTAINER FOR RECEIVING A NUTRIENT OR PHARMACEUTICAL LIQUID

FIG 2



(57) Abstract: The invention relates to a container for receiving a nutrient or pharmaceutical liquid, comprising a volume (14) that can be filled with the nutrient liquid and a first and a second flexible wall (11, 12) delimiting the volume (14). According to the invention, the first and/or the second flexible wall (11, 12) comprises a polyester containing film (110) at least partially covered by a aluminium and/or silicon containing coating (120). The aluminium and/or silicon containing coating (120) is arranged on the side of the polyester containing film (110) that faces towards the volume (14) and a polypropylene containing film (150) is arranged on the coated side of the polyester containing film (110) and a further polyester containing film (130) is arranged on the non-coated side of the polyester containing film (110). The invention also relates to a method for fabricating a container (1) for receiving a nutrient or pharmaceutical liquid.

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15 **Container for receiving a nutrient or pharmaceutical liquid and method for
fabricating a container for receiving a nutrient or pharmaceutical liquid**

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Description

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The invention relates to a container for receiving a nutrient or pharmaceutical liquid according to the preamble of claim 1 and a method for fabricating a container for receiving a nutrient or pharmaceutical liquid according to the preamble of claim 15.

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Containers in the form of flexible bags for receiving a nutrient liquid, e.g. for enteral nutrition, are known from the prior art. For example, EP 1 765 254 B1 discloses a film bag filled with an enteral nutrient liquid. The bag comprises a first and a second film welded to one another to delimit a volume that is filled with the nutrient liquid.

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It is an object of the invention to provide an improved liquid receiving container and a method for fabricating such a container.

According to the invention, a container for receiving a nutrient or pharmaceutical liquid is provided, the container comprising a volume that can be filled with the nutrient liquid; and

a first and a second flexible wall delimiting the volume, wherein the first and/or the second flexible wall comprises a polyester containing film which is at least partially or completely covered by an aluminium and/or silicon containing coating. The aluminium and/or silicon containing coating is arranged on the side of the polyester containing film that faces towards the volume. A polypropylene containing film is arranged on the coated side of the polyester containing film and a further polyester containing film is arranged on the non-coated side of the polyester containing film. By placing the aluminium and/or silicon containing coating between the polypropylene containing film and the polyester containing layers, the film properties are improved. The polyester containing film and/or the further polyester containing film is a film comprising polyester or consisting of polyester.

The first and the second flexible wall are e.g. provided as congruent separate material layers that are joined to one another, for example, by arranging the material layers one above the other and welding them together along their circumferential edges. However, it is also conceivable that the first and the second flexible wall are integrally connected to one another, i.e. a single initial material layer is used that is folded, wherein the folded portions form the first and the second flexible wall, respectively.

In particular, the container according to the invention is formed as a bag. The bag, for example, may be flat, light-weight and unbreakable such that it is easy to be transported and thus could be carried along by mobile patients during bolus feedings. In one embodiment the bag is a stand-up bag.

According to an embodiment of the invention, the aluminium and/or silicon containing material used for coating of the first and/or the second flexible wall comprises aluminium and/or silicon oxide or consists of aluminium and/or silicon oxide. For example, the aluminium and/or silicon containing coating is arranged only on the side of the polyester containing film that faces towards the fillable volume of the container.

Further, the first and/or the second container wall is a multi-layer wall, i.e. besides the coated polyester containing film the first and/or the second wall comprise at least one further layer (e.g. a further film). In particular, the layer structure of first and the second wall is identical, i.e. the first wall may consist of the same films as the second wall.

The aluminium and/or silicon coating may be arranged only on the side of the polyester containing film that faces towards the fillable volume of the container. For example, the coated polyester containing film is, preferably directly, sandwiched between two material layers, wherein the two layers may be joined (e.g. laminated) to the coated polyester containing film. The first and/or the second wall of the container thus may consist of exactly three layers. However, more than three layers may be provided.

The one of the material layers that is arranged on the coated side of the polyester containing film is a polypropylene containing film, wherein the polypropylene containing film may form an inner side of the container wall that after filling the container with the liquid may come into contact with the liquid. Preferably the polypropylene containing film is fabricated according to chapter 3.1.6 of the Pharmacopoea Europaea. Moreover, the polypropylene containing film may be joined to the aluminium and/or silicon containing coating by means of an adhesive (see below).

The one of the material layers that is arranged on the non-coated side of the polyester containing film is a further polyester containing film, wherein, in particular, the composition of the further polyester containing film differs from the composition of the coated polyester containing film. For example, the further polyester containing film forms the outer side of the container wall which is exposed to the environment.

- In one embodiment the aluminium and/or silicon containing coating has a thickness or weight of 0.05 g/sqm to 0.15 g/sqm. . One exemplary weight is approximately 0.1 g/sqm.
- In one embodiment the, preferably inner, polyester containing film has a thickness of 1 µm to 30 µm, preferably 10 µm to 15 µm. One exemplary thickness is approximately 12 µm.
- In one embodiment the outer polyester containing film has a thickness of 1 µm to 30 µm, preferably 10 µm to 15 µm. One exemplary thickness is approximately 12 µm.
- In one embodiment the polypropylene containing film has a thickness of 50 µm to 200 µm, preferably 100 µm to 120 µm. One exemplary thickness is approximately 110 µm.

Further, text and/or graphic information may be printed on the further polyester containing film, wherein e.g. flexographic printing is used comprising transferring liquid ink to a surface of the further polyester containing film. The flexographic printing

technology may result in a print that prior and even after sterilization of the container may be glossy and rub resistant. Furthermore, the liquid ink used for flexographic printing may be suitable for retortable applications and may also be used in combination with solvent based adhesives that may be employed for joining the film layers of the container to one another (see below).

The material layers sandwiching the coated polyester containing film may be joined to the coated polyester containing film by an adhesive that may be sterilizable and/or boil-proof. For example, the adhesive is a solvent-based two-component system, which, for example, has a high initial tack. The adhesive may comprise polyurethane (e.g. comprising aliphatic isocyanates). In particular, the adhesive is suited for joining the above-mentioned polypropylene containing film to the aluminium and/or silicon containing coating of the polyester containing film and may also be used to join the further polyester containing film to the non-coated side of the polyester containing film.

Further, the container walls may comprises other layers (e.g. films) such that the adhesive may also be suited for the lamination of transparent films, metallized films or aluminium films with or without sandwich printing. It is noted that when films of the container are printed (see above), ink may be used that permits the film to be laminated by the adhesive.

According to a further embodiment, the container according to the invention comprises a connector for connecting a hose line to the container, wherein the connector comprises a tube portion fabricated from a polypropylene containing material and a cap portion also fabricated from a polypropylene containing material. The tube portion may be configured to receive an ending of the hose, wherein the ending may comprise a spike for opening a sealing element of the connector. The cap portion closes the connector and may comprise breakable part that can be broken to open the connector for the insertion of the connecting hose. For example, the connector is formed as described in European patent EP 1 765 254 B1, which in that respect is enclosed by reference herewith.

By means of the connector a closed system may be provided avoiding external contamination and sealing the fillable volume from outside air. Further, the container may be sterilized at higher temperatures (e.g. above 100°C, for example, at 121°C) essentially without structural deterioration or thermal deformation. Preferably all materials used in the container may be sterilized at higher temperatures (e.g. above 100°C, for

example, at 121 °C) essentially without structural deterioration or thermal deformation. Further, the container may be colour coded to reduce the risk of mixing up nutrient or pharmaceutical liquids. Also, the container may be latex free such that the risk of allergies is reduced. The container may further be PVC free to provide an environmental friendly and recyclable product.

The polypropylene containing material used for fabricating the tubular portion and/or the cap may be a polypropylene material as defined in chapter 3.1.6 of the Pharmacopoea Europaea.

As already mentioned above, the connector comprises a sealing element clamped or arranged between the tube portion and the cap portion and sealing the channel in the connector. The sealing element may be a membrane and may be formed from a material comprising an elastomer or may consist of such a material. For example, the elastomer used for fabricating the sealing element is a material defined in chapter 3.2.9 type I of the Pharmacopoea Europaea, for instance a material comprising polyisoprene or consisting of polyisoprene.

The invention also relates to a method for fabricating a container for receiving a nutrient or pharmaceutical liquid, in particular according to one of the preceding claims, comprising producing a first and a second flexible wall for delimiting a volume that can be filled with the nutrient liquid, wherein producing the first and/or the second flexible wall comprises providing a polyester containing film and at least partially covering the film with an aluminium and/or silicon containing coating wherein the aluminium and/or silicon containing coating is arranged on the side of the polyester containing film that faces towards the volume and a polypropylene containing film is arranged on the coated side of the polyester containing film and a further polyester containing film is arranged on the non-coated side of the polyester containing film.

Embodiments of the invention are described in more detail hereinafter with reference to the drawings. These show:

FIG. 1 a side view of a container according to an embodiment of the invention;
and

FIG. 2 a sectional view of a flexible wall of a container according to an embodiment of the invention.

According to Figure 1, a bag like container 1 according to the invention comprises a first
5 and a second flexible wall 11, 12, wherein the flexible walls 11, 12 are congruently
arranged one above the other such that only one of the flexible walls (wall 11) is visible in
Fig. 1.

The first and the second flexible wall 11, 12 are tightly welded to one another along a
10 welding seam 13 extending along peripheral edges 111, 121 of the first and the second
flexible wall 11, 12 such that the walls 11, 12 delimit a volume 14 that can be filled with a
liquid, e.g. a nutrient or pharmaceutical liquid. Both the first and the second flexible wall
11, 12 comprise a polyester containing film coated with a silicon and/or aluminium
containing material (see Fig. 2).

15 Container 1 further comprises a connector 2 for connecting a hose line (not shown) to the
container 1 such that liquid can be extracted from the container 1 via the hose line. The
connector 2 comprises a tube portion 22 (a so-called port 22) and a cap portion 21. The
cap portion 21 is latched to the tube portion 22. The cap portion 21 closes the access
20 channel in the tube portion 22. The tube portion 22 comprises a lower part 222 which
fixed or welded to the container 1 and an upper part 221 which is connected with the cap
portion 21. The upper part 221 extends partially into the cap portion 21 and is therefore
only partially visible in figure 1. The lower part 222 of the tube portion 22 comprises wing
like protrusions 223 which are laminated between the first and the second flexible wall
25 11, 12.

Further, the connector 2 comprises a sealing element in form of a membrane (not visible
in the figures) sealing a channel in the connector 2, wherein the cap portion 21 and the
membrane close the tube portion 22 and therefore the connector 2 and thus seal the
30 fillable volume 14. The cap portion 21 comprises on the top a break- or twist-off part 211
which is configured to be broken off by twisting and/or tilting to allow the insertion of a
spike to connect the hose line with the connector 2. Using the spike the membrane can
be perforated such that liquid can be extracted from the volume 14 via the connector 2
and the hose line. Details of the connector 2 are described in European patent EP 1 765
35 254 B1 as already set forth above.

According to the embodiment shown in Fig. 1, the tube portion 22 of the connector 2 and the cap portion 21 are formed from polypropylene, in particular as defined in chapter 3.1.6 of the Pharmacopoea Europaea and comprising white pigment. The membrane 23 is formed from an elastomer, e.g. from the type 1 elastomer defined in chapter 3.2.9 of the Pharmacopoea Europaea, for instance polyisoprene.

A possible structure of the flexible walls 11, 12 of the container 1 is illustrated in Fig. 2, wherein Fig. 2 shows a part of a cross section of one of the flexible walls 11, 12.

The walls 11, 12 as mentioned above each comprise a polyester containing film in the form of a polyester film 110 covered by a silicon and/or aluminium containing coating 120 (having a thickness of e.g. less than 20 μm , for example having a thickness of about 12 μm). The silicon and/or aluminium containing coating 120 is arranged on a side of the polyester film 110 that faces towards the inner volume 14 of the container 1. In one embodiment the silicon and/or aluminium containing coating 120 is a silicon oxide and/or aluminium oxide containing coating 120. In another embodiment the coating 120 is a silicon oxide coating 120 only.

An outer side of the walls 11, 12 is formed by a further polyester containing film in the form of an outer polyester film 130 having a composition different from the composition of the coated polyester film 110. The outer polyester film 130 is joined to the non-coated side of polyester film 110 by means of a sterilizable and/or boil-proof adhesive 140, which may be a solvent-based two-component system (e.g. comprising polyurethane). The outer polyester film 130 may have a thickness of 10 – 20 μm , e.g. of 12 μm .

Furthermore, the flexible walls 11, 12 each comprise a polypropylene containing film in the form of an inner polypropylene film 150 (e.g. fabricated according to chapter 3.1.6 of the Pharmacopoea Europaea). Inner polypropylene film 150 is bonded to the silicon and/or aluminium containing coating 120 of polyester film 110 by an adhesive 140' which may be identical to adhesive 140 used to join the outer polyester film 130 to the non-coated side of polyester film 110.

It is noted that in the embodiment depicted in Fig. 2 the flexible walls 11, 12 each comprise exact three films (and the silicon coating of the inner polyester film). However, the invention also covers containers having flexible walls that comprise further films, i.e.

more than three film layers. Also, it is not necessary that the layer structure of the flexible walls 11, 12 is identical.

5 References numbers:

1	Container
2	Connector
11, 12	flexible wall
13	welding seam
14	Volume
110	polyester film
111, 112	peripheral edge
120	silicon oxide coating
130	outer polyester film
140, 140'	Adhesive
150	inner polypropylene film
21	cap portion of the connector
211	break-off part of the cap portion
22	tube portion or port of the connector
221	upper part of the tube portion
222	lower part of the tube portion
223	wing like protrusion of the tube portion

Claims

1. A container for receiving a nutrient or pharmaceutical liquid, comprising
 - a volume (14) that can be filled with the nutrient liquid; and
 - 5 - a first and a second flexible wall (11, 12) delimiting the volume (14),
the first and/or the second flexible wall (11, 12) comprises a polyester containing film (110) at least partially covered by an aluminium and/or silicon containing coating (120), the aluminium and/or silicon containing coating (120) is arranged on the side of the polyester containing film (110) that faces towards the volume (14),
 - 10 wherein a polypropylene containing film (150) is arranged on the coated side of the polyester containing film (110) and a further polyester containing film (130) is arranged on the non-coated side of the polyester containing film (110).
2. The container as claimed in claim 1, wherein the aluminium and/or silicon containing
15 coating (120) comprises aluminium and/or silicon oxide or consists of aluminium oxide and/or of silicon oxide.
3. The container as claimed in claim 1 or 2, wherein the aluminium and/or silicon containing coating (120) is arranged only on the side of the polyester containing film
20 (110) that faces towards the volume (14).
4. The container as claimed in one of the preceding claims, wherein the coated polyester containing film (110) is directly sandwiched between two material layers wherein one of the two material layers that is arranged on the coated side of the polyester
25 containing film (110) is the polypropylene containing film (150) and wherein one of the two material layers that is arranged on the non-coated side of the polyester containing film (110) is the further polyester containing film (130).
5. The container as claimed in one of the preceding claims, wherein the polypropylene
30 containing film (150) is a contact layer for the filled nutrient liquid.
6. The container as claimed in one of the preceding claims, wherein the further polyester containing film (130) is an exterior layer of the wall.
- 35 7. The container as claimed in one of the preceding claims, wherein the composition of the further polyester containing film (130) is different from the composition of the coated polyester containing film (110).

8. The container as claimed in one of the preceding claims, wherein the material layers and/or the polypropylene containing film (150) and/or the further polyester containing film (130) are joined to the coated polyester containing film (110) by a sterilizable and/or boil-proof adhesive (140, 140').
- 5 9. The container as claimed in claim 8, wherein the adhesive (140, 140') comprises polyurethane.
- 10 10. The container as claimed in one of the preceding claims, further comprising a connector (2) for connecting a hose line to the container (1), wherein the connector (2) comprises a tube portion (22) fabricated from a polypropylene containing material and a cap portion (21) also fabricated from a polypropylene containing material.
- 15 11. The container as claimed in claim 10, wherein the polypropylene containing material is a polypropylene material defined in chapter 3.1.6 of the Pharmacopoea Europaea.
12. The container as claimed in claim 10 or 11, wherein the connector (2) comprises a sealing element clamped between the tube portion (22) and the cap portion (21).
- 20 13. The container as claimed in claim 12, wherein the sealing element (4) is formed from a material comprising an elastomer, wherein the elastomer is a material, preferably comprising polyisoprene or consisting of polyisoprene, defined in chapter 3.2.9 type I of the Pharmacopoea Europaea.
- 25 14. The container as claimed in one of the preceding claims, wherein the aluminium and/or silicon containing coating (120) has a thickness of 0.05 g/sqm to 0.15 g/sqm and/or wherein the polyester containing film (110) has a thickness of 1 µm to 30 µm and/or wherein the further polyester containing film (150) has a thickness of 1 µm to 30 µm and/or wherein the polypropylene containing film (150) has a thickness of 50 µm to 200 µm.
- 30 15. Method for fabricating a container (1) for receiving a nutrient or pharmaceutical liquid, in particular according to one of the preceding claims, comprising producing a first and a second flexible wall (11, 12) for delimiting a volume (14) that can be filled with the nutrient liquid, wherein
- 35 producing the first and/or the second flexible wall (11, 12) comprises providing a polyester containing film (110) and at least partially covering the film with an aluminium and/or silicon containing coating (120) wherein the aluminium and/or silicon containing coating (120) is arranged on the side of the polyester containing

film (110) that faces towards the volume (14) and a polypropylene containing film (150) is arranged on the coated side of the polyester containing film (110) and a further polyester containing film (130) is arranged on the non-coated side of the polyester containing film (110).

FIG 1

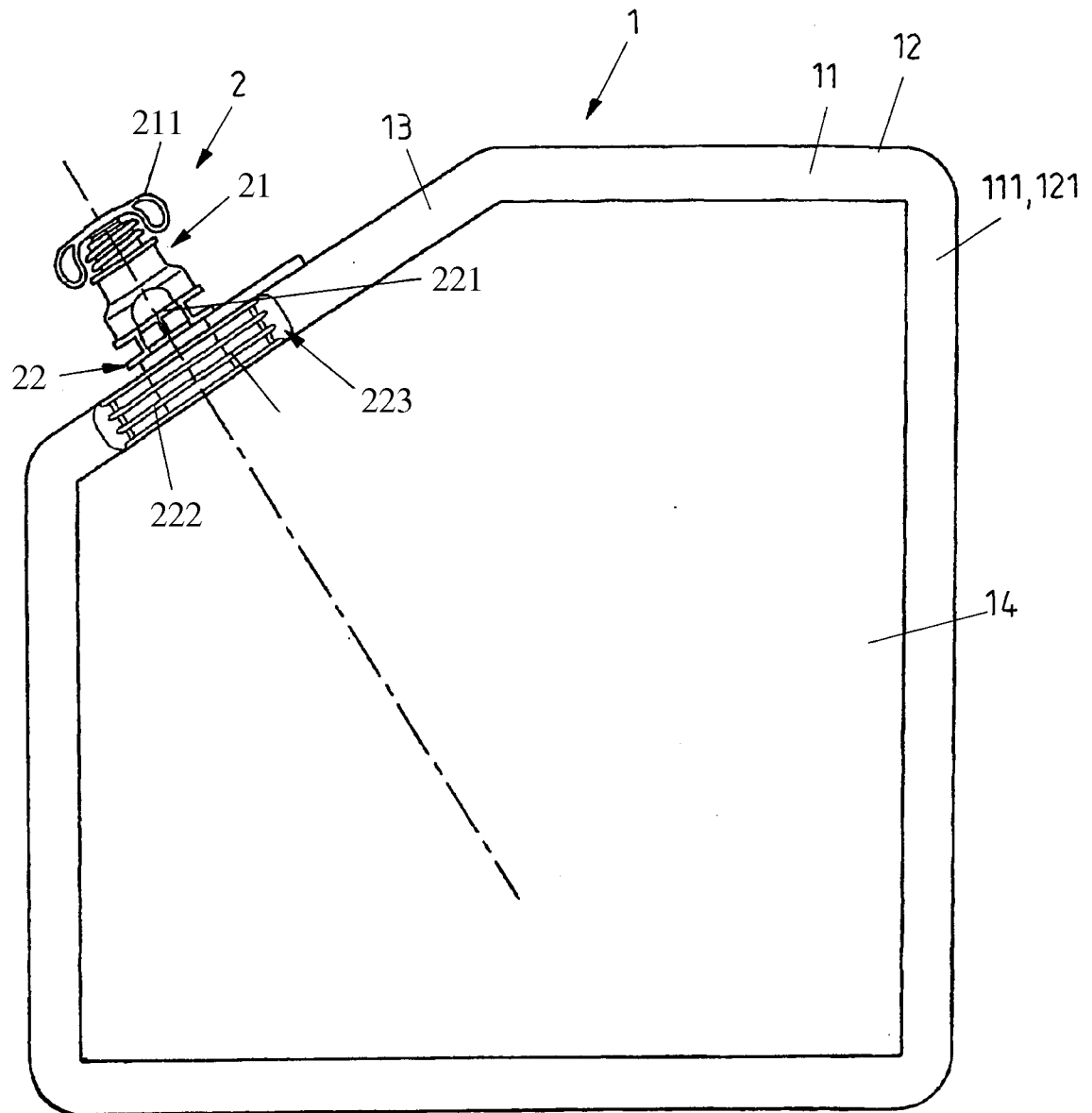
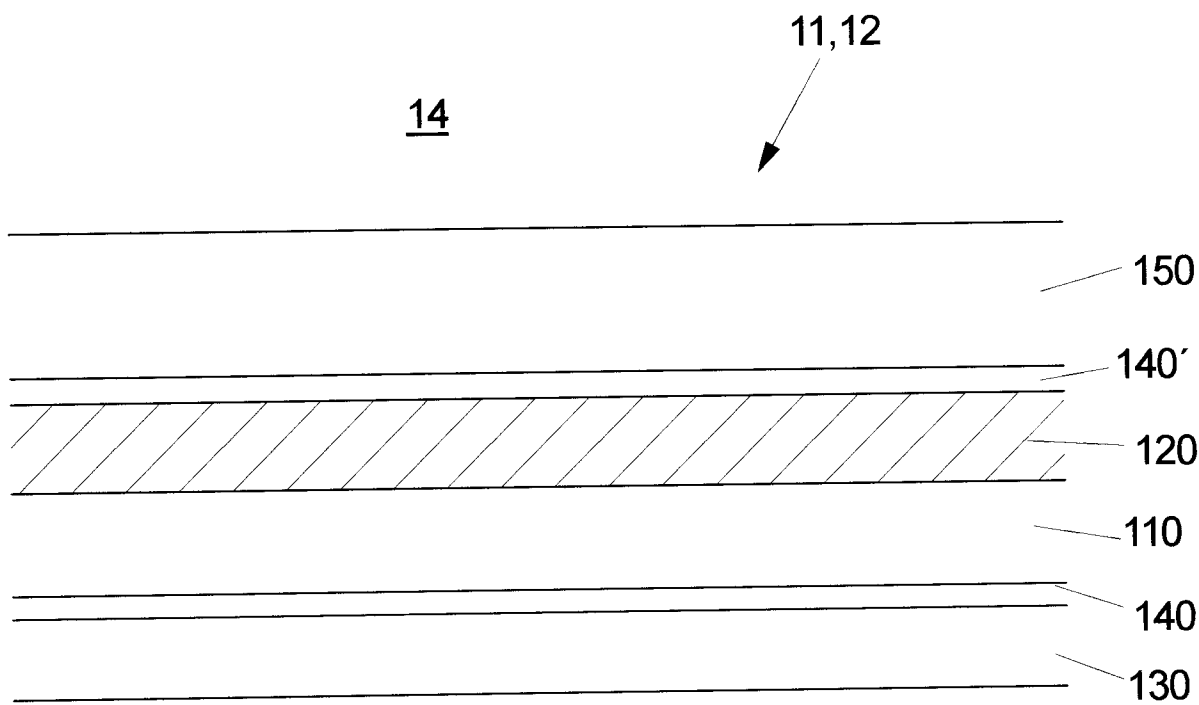


FIG 2



INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER INV. B32B27/08 A61J1/10 B32B27/32 B32B27/36 ADD.		
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) B32B A61J		
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 practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "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 "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 "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 "&" document member of the same patent family		
Date of the actual completion of the international search 3 December 2014		Date of mailing of the international search report 10/12/2014
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Hillebrand, Gerhard

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Information on patent family members

International application No

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