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(54) **CONTAINER WITH SPACED APART LABEL**

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WO-A-97/11003 WO-A-98/04477
WO-A-98/14189 US-A- 4 367 821**

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Description

[0001] This invention relates to containers and in particular to containers with plastics material walls whose contents can undesirably permeate through the container walls or which are sensitive to ingress of material through the container walls. In particular the invention relates to such containers when used for medicaments.

[0002] Plastics, e.g. polyethylene, polypropylene, polyethyleneterephthalate, containers are commonly used to contain medicaments. If a label or shrink sleeve is applied to the outer wall of such a container the adhesive which binds the label or sleeve onto the container surface or alternatively the printing ink which is used when information is printed directly onto the container surface may permeate through the wall thereby contaminating the contents of the container, potentially leading to harmful effects. The term "label" used hereinafter, unless specifically distinguished, includes labels attached by an adhesive, shrink sleeves and matter printed directly onto a container wall.

[0003] When the content of the container is a medicament, it may be necessary to conduct a stability study/trial of any new labelling material applied to the container wall so as to ensure that the medicament is not compromised by any aspect of the packaging, including the properties of the adhesive and printing inks. Such trials can be expensive and time-consuming. New adhesives, printing inks or plastics materials may have to be sought which do not give rise to the problem discussed above, although this approach is both time consuming and expensive, particularly if clinical trials are required to prove that the new adhesive or ink does not cause contamination of the contents. Conversely the contents of such a plastic walled container, particularly solvents, may permeate through the walls and may have a deleterious effect on a label on the outer surface of the container e.g. causing a label fixed by adhesive to become detached or to discolour the printing ink. Materials for container walls which are non-permeable are known, in particular glass and metal, but these have the disadvantage of fragility and cost.

[0004] US 4367821 discloses a container in which a label is attached to an external skirt spaced apart from a container wall, but possible contents for the container, or the problems caused by label material permeating through the container wall, are not contemplated.

[0005] A product comprising a double walled container is disclosed in document WO-A-9 711 003.

[0006] It is an object of the present invention to at least partly provide a solution to the problem of contamination arising from permeation through a container wall of contaminants such as label adhesives or printing ink(s), and/or permeation in the reverse direction of container contents.

[0007] According to this invention a product according to claim 1 is provided.

[0008] The container construction of the invention enables the contents of the container to be directly enclosed by the inner wall, and to be in contact with the inner surface of the inner wall, yet not being vulnerable to contamination by label material such as adhesives or printing ink applied to the outer wall, should this material be liable to permeate through the outer wall. Consequently the adhesive or ink cannot contaminate the contents by penetration of the wall, and vice versa the content cannot penetrate the wall and affect the label.

[0009] In some places the internal cavity may be directly enclosed by parts of the outer wall and may be in contact with the outer wall, but the label need not be applied to the outer surface of these parts of the outer wall, but only to those parts of the outer wall the inner surface of which is not in contact with the contents.

[0010] In a first embodiment the outer wall of the container may comprise a skirt portion attached to, e.g. integral with or fitted onto, the inner wall, and having a skirt part spaced apart from the inner wall.

[0011] This skirt portion may be an upper skirt for example surrounding an upper part of the inner wall. In this embodiment the inner wall may comprise the upper part of the body and may include the mouth opening of the container, for example, the inner wall may define and surround the rim of the mouth opening of the container. The skirt portion may alternatively be a lower skirt surrounding the lower part, e.g. the bottom of the container body. In this embodiment the container may have both upper and lower skirts.

[0012] In this first embodiment the label may be attached to the outer surface of the skirt part, whether an upper or lower skirt, or both upper and lower skirts at a place where the skirt part is spaced apart from the inner wall.

[0013] The upper or lower skirt portion may have a label fixed to its outer surface by adhesive or alternatively information may be printed directly onto the skirt portion. The abovementioned upper and lower skirts may depend from a part of the body wall which directly encloses the contents of the container i.e. so that the contents of the container are in direct contact with the inner surface of this part of the body wall, but are not in contact with the inner surface of the upper and/or lower skirt portion.

[0014] The container may be of any shape appropriate for its intended use, for example generally cylindrical, e.g. bottle shaped. The term "cylindrical" as used herein includes true cylinders i.e. a shape having straight longitudinal sides and a circular cross section, with the longitudinal axis of the cylinder passing through the centre of the circular section, and also distorted cylinders, e.g. shapes with convex bulging longitudinal sides e.g. "barrel" shapes, shapes with concave sides, i.e. wider at the cylinder ends than at a waist. Also the term "cylinder" includes such shapes with oval or oblate circular cross section.

[0015] When the container is of generally cylindrical shape, then the upper and lower skirts may also be of

generally cylindrical shape e.g. of substantially the same cross sectional shape as the container. When the container is provided with upper or lower skirts these may be made integrally with the container body or may be separately fitted to the container body, for example by welding or a physical connection such as a snap fit.

[0016] The container of the invention may for example be of multi-part construction, e.g. in lower and upper container parts which fit together with a seal which does not allow leakage or contamination of the contents, and such lower and upper container parts may comprise respective lower and upper inner and outer wall parts of the container which fit together when the upper and lower container parts are fitted together. In such a construction the respective upper and lower wall parts may both fit together with such a seal.

[0017] The container of this invention may be made of conventional plastics, e.g. polyethylene, polypropylene or polyethyleneterephthalate. Suitable wall thicknesses for the inner wall may be ca. 1 - 2 mm, and for the outer wall ca. 1 - 2.5 mm. The inner wall may benefit from protection from the outer wall and may consequently be relatively thin.

[0018] The container of the invention is suitable for a wide variety of medicament contents, particularly fluids such as liquid, gel, cream or paste medicaments i.e. which incorporate a solvent vehicle. Such medicaments may for example be suitable for topical applications or for applications to selected parts of the body e.g. a nasal medicament. Such medicaments may be applied as a spray, droplet or surface smear to such a selected part of the body. Examples of such medicaments are liquid formulations based on known pharmaceutically acceptable oily vehicles such as monoglycerides, such as mono-olein and mono-linolein, phospholipids such as phosphatidyl cholines, and galactolipids such as glyceryl diglycerides. Typically such monoglycerides may be long-chain fatty acid monoglycerides, optionally also containing a long-chain diglyceride. Such mono- and di- glycerides may for example be blends of different long-chain fatty acid mono- and di- glycerides. Examples of such fatty acid monoglycerides include glycerol mono-oleate, glycerol monopalmitate and glycerol monostearate. Suitable commercially available examples of such products include those available under the trade names MYVEROL, such as MYVEROL, MYVATEX, MYVAPLEX and GMORPHIC 80 respectively. Another example of such a material is ARLACEL 186, which in addition to glycerol mono-oleate includes propylene glycol. Typically in such long-chain monoglycerides the major fatty acid component is a C₁₈ saturated, mono-unsaturated or polyunsaturated fatty acid. Such oily vehicle based medicaments may also include fatty acid triglycerides, typically a vegetable oil, for example as diluents with the above-mentioned fatty acid monoglycerides. Examples of such include coconut oil, e.g. fractionated coconut oil. Commercially available examples of such triglyceride diluent materials include caprylic /

capric triglyceride (Tricaprylin). Examples of such materials which are commercially available include those available under the trade names MYRITOL, CAPTEX and MIGLYOL. Examples of such oily vehicles are for example disclosed in WO98/14189A (SmithKline Beecham PLC) the contents of which are included herein by way of reference. The container of the invention is suitable for use with a wide range of active compounds dissolved or dispersed in such a vehicle. A particular example of such an active compound is the compound the antibiotic Mupirocin (Pseudomonic acid, "Bactroban™") typically in the form of calcium mupirocin. An example of such a mupirocin formulation suitable for use as a nasopharyngeal spray formulation is also disclosed in WO98/14189A, typically comprising fractionated coconut oil (i.e. medium chain length triglycerides) e.g. the commercial product MIGLYOL, glycerol mono-oleate e.g. the commercial product MYVEROL 18-99, powdered lemon juice flavour, and micronised calcium mupirocin. The container of the invention is for example provided for, or containing, such a formulation.

[0019] The container may be otherwise generally conventional and also provided with a suitable closure means for its mouth opening such as a snap fit or screw threaded cap. The container may further comprise delivery means to deliver fluid contents to for example a nozzle, comprised by the mouth opening of the container, such as a feed tube leading from the mouth opening to the vicinity of the bottom of the container. Such delivery means may comprise for example a pump, typically of a known type used to pump liquid medicaments, such as an air lift pump, leading to an outlet for the medicament such as a spray nozzle.

[0020] For example the container may be a nasal spray container provided with means to deliver its medicament content to the nasal area of a user.

[0021] The container may be made by conventional methods such as blow moulding or injection moulding. Another aspect of the invention provides moulds for making containers of the present invention and furthermore a process e.g. an injection moulding or blow moulding process using such moulds for making the container of the invention.

[0022] The container will now be described by way of example only with reference to the accompanying drawing in which Figs. 1 shows a container which forms not part of the invention and only Fig. 2 shows a container of the invention.

[0023] Referring to Fig. 1, a container which forms not part of this invention is shown in longitudinal section. The container comprises a bottle-shaped container 11 of generally cylindrical shape with a generally conical bottom with its concave side toward the interior of the container, defined by a container wall 12. The container 11 is provided with pairs of spaced apart inner and outer walls, being a lower pair of inner 13 and outer 14 walls and an upper pair of inner 15 and outer 16 walls. The outer wall of each of these pairs 13, 14 and 15, 16 re-

spectively is in the form of a lower skirt portion 17 and an upper skirt portion 18. The lower skirt portion 17 depends from the container wall 12 and surrounds the conical bottom of the container 11. This conical bottom consequently comprises the inner wall 13.

[0024] A label 19 is attached by adhesive to the outer surface of the outer wall 14. An upper skirt portion 18 extends from the container wall 12 and also has a label 19 applied to it by adhesive. Liquid contents 110 are within the container wall 12. By locating the label 19 only on the outer wall 14 of the lower skirt 17 and/or the upper skirt 18, and not on an outer surface of the container wall 12 of which the inner surface is in contact with the contents 110, the liquid contents 110 and label 19 are consequently not facing each other on opposite sides of the same region of container wall 12. Therefore adhesive from the label 19 cannot permeate through the container wall 12 and contaminate the contents 110 and vice versa the contents 110 cannot leak through container wall 12 and affect the label 19.

[0025] The lower skirt portion 17 is made integrally with the container wall 12 and integrally joins the container wall at its upper extremity. The upper skirt portion 18 is made separately and is fitted to the upper part of the container wall 12 by a snap fit fitting at 111.

[0026] Alternatively the lower skirt 17 may be made separately and fitted to the container 11 or the upper skirt 18 may be made integrally with the container 11. The container 11 is provided with a mouth opening 112 which has a rim defined by the upper part of the inner wall 15 of the container wall 12. The container 11 is also provided with a delivery means 113 (generally) comprising a nozzle 114 and a feed tube 115. The nozzle 114 fits tightly onto the mouth opening 112 of the container by a snap fitting. The feed tube 115 reaches down toward the lowest part of the conical bottom of the container and feeds liquid to the nozzle 114 from the body 11 in a known manner for example via a pump mechanism 116 or by making the container wall 12 of compressible material and squeezing the container. The container 11 is closed by a closure 117 cover. As shown in the sectional view Fig. 1B about the line B-B the container 11 is oval in cross section.

[0027] Referring to Fig. 2 a container of the invention is shown which comprises a lower part container 21 (overall) which has a base wall 22 and lower part side walls 23, 24 extending upwardly from the base wall toward an upper mouth opening 25 of the container 21. The side walls 23, 24 are a continuous double wall comprising spaced apart inner 23 and outer 24 walls extending from the base wall 22 to the height of the mouth opening 25. The inner 23 and outer 24 are substantially cylindrical (as seen in Fig. 2B having an oval cross section, and are substantially concentric and coaxial. The base wall 22 is a continuous base wall linking the inner 23 and outer 24 walls and closing the space 26 between them. The container construction of the invention enables contents (not shown) in the internal cavity 27 of the

container to be directly enclosed by the inner wall 23, and to be in contact with the inner surface of the inner wall 23, yet not being vulnerable to contamination by label materials 28 such as adhesives or printing ink applied to the outer wall 24. The internal cavity 27 is also directly enclosed by the base wall 22 where this forms a part of the outer wall 24, but the label is not applied to the outer surface of the base wall 22. The container 21 is made of polypropylene and the inner wall is ca. 1 - 1.5 mm thick, and the outer wall ca. 1.5 - 2.0 mm thick. The volume of the internal cavity 27 is ca 10 - 25 ml in the example illustrated.

[0028] The container 21 is suitable for a liquid medicament which incorporates a solvent vehicle, such as the oily vehicles described above. As shown the container 21 is a nasal spray dispenser. The container is provided with a pump 29 (generally), typically an air lift pump, to deliver liquid contents to a nozzle 210, via a feed tube leading from the mouth opening to the vicinity of the bottom of the container. The pump 29 is provided as part of an upper part assembly 212 (generally), including upper part inner and outer walls respectively 23A and 24A, and provided with fittings 213A enabling it to fit by a push action onto the lower part container 21 at corresponding fittings 213B, and to be retained thereon by a friction and snap fit. The fitting together of the fittings 213A and 213B form a seal which prevents leakage and contamination of the contents in the cavity 27.

[0029] The nozzle 210 is covered by a cover closure 214 such that the feed tube 211 fits into the cavity 27 and reaches down to a point near its bottom. As shown in the half sectional view Fig. 2B about the line B-B the container 21 is oval in cross section.

Claims

1. A product comprising a double walled container (21), having a base wall (22) and side walls (23,24) extending upwardly from the base wall (22) toward an upper mouth opening (25) of the container, and the side walls (23,24) are in the form of a double wall comprising spaced apart inner (23) and outer (24) walls, made of a plastics material, a label (28) being located on the outer surface of the outer wall (24), the body (21) having an internal cavity (27) containing a medicament content and being bounded at least in part by the inner wall (23), **characterised in that** the base wall (22) is a continuous base wall (22) linking the inner and outer walls (23,24) and closing the space (26) between them.
2. A product according to claim 1, **characterised in that** the internal cavity (27) is directly enclosed by parts of the outer wall (24) and is in contact with the outer wall (24), but the label (28) is applied to a part of the outer wall (24) the inner surface of which is not in contact with the contents.

3. A product according to claim 1 or 2 **characterised in that** the side walls (23,24) are in the form of a continuous double wall (23,24) extending the whole height of the internal cavity (27) from the base wall (22) to the mouth opening (25).

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4. A product according to any preceding claim **characterised by** substantially cylindrical inner and outer walls (23,24), which are substantially concentric and coaxial.

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5. A product according to any preceding claim **characterised by** lower (21) and upper (212) container parts which fit together with a seal (213A,213B) which does not allow leakage or contamination of the contents, such lower and upper container parts (21, 212) comprising respective lower (23,24) and upper (23A,24A) inner and outer wall parts of the container which fit together when the upper (23A, 24A) and lower (23,24) container parts are fitted together.

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6. A product according to any preceding claim made of plastics material and having an inner wall (23) thickness ca. 1 - 2 mm, and an outer wall thickness ca. 1 - 2.5 mm.

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7. A product according to any preceding claim **characterised in that** the medicament content is a fluid which incorporates a solvent vehicle.

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8. A product according to claim 7 **characterised in that** the solvent vehicle is a pharmaceutically acceptable oily vehicle.

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9. A product according to claim 8 **characterised in that** the oily vehicle is a monoglyceride, phospholipid, or a galactolipid.

10. A product according to claim 9 **characterised in that** the oily vehicle is selected from glycerol monooleate, glycerol monopalmitate and glycerol monostearate.

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11. A product according to claim 8, 9 or 10 **characterised by** containing a long-chain diglyceride.

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12. A product according to any one of claims 8 to 10 containing a fatty acid triglyceride.

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13. A product according to claim 12 **characterised in that** the fatty acid triglyceride is caprylic / capric triglyceride (Tricaprylin).

14. A product according to any one of the preceding claims **characterised in that** the medicament content comprises calcium mupirocin, fractionated coconut oil, and glycerol mono-oleate.

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15. A product according to any preceding claim being a nasal spray container (21) provided with means (29,210) to deliver its medicament content to the nasal area of a user.

Patentansprüche

1. Produkt, das einen doppelwandigen Behälter (21) aufweist, der eine Bodenwand (22) und Seitenwände (23,24) aufweist, die sich von der Bodenwand (22) nach oben zu einer oberen Mundöffnung (25) des Behälters erstrecken, und die Seitenwände (23,24) liegen in der Form einer Doppelwand vor, die voneinander beabstandete innere (23) und äußere (24) Wände aufweist, die aus Kunststoffmaterial bestehen, wobei ein Etikett (28) auf der Außenfläche der äußeren Wand (24) angeordnet ist, wobei der Körper (21) einen inneren Hohlraum (27) aufweist, der einen Medikamenteninhalt enthält und mindestens teilweise durch die innere Wand (23) gebunden ist, **dadurch gekennzeichnet, daß** die Bodenwand (22) eine durchgehende Bodenwand (22) ist, die die inneren und äußeren Wände (23,24) verbindet und den Raum (26) zwischen ihnen abschließt.

2. Produkt nach Anspruch 1, **dadurch gekennzeichnet, daß** der innere Hohlraum (27) durch Teile der äußeren Wand (24) direkt umschlossen ist und in Kontakt mit der äußeren Wand (24) steht, das Etikett (28) jedoch auf ein Teil der äußeren Wand (24) aufgebracht ist, deren Innenfläche nicht in Kontakt mit dem Inhalt steht.

3. Produkt nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** die Seitenwände (23,24) in der Form einer durchgehenden Doppelwand (23,24) vorliegen, die sich über die gesamte Höhe des inneren Hohlraums (27) von der Bodenwand (22) zur Mundöffnung (25) erstreckt.

4. Produkt nach einem der vorhergehenden Ansprüche, **gekennzeichnet durch** im wesentlichen zylindrische innere und äußere Wände (23,24), die im wesentlichen konzentrisch und koaxial verlaufen.

5. Produkt nach einem der vorhergehenden Ansprüche, **gekennzeichnet durch** untere (21) und obere (212) Behälterteile, die mit einer Dichtung (213A, 213B) zusammenpassen, die kein Austreten oder keine Verunreinigung des Inhalt zuläßt, wobei solche unteren und oberen Behälterteile (21,212) jeweilige untere (23,24) und obere (23A,24A) innere und äußere Wandteile des Behälters aufweisen, die zusammenpassen, wenn die oberen (23A,24A) und unteren (23,24) Behälterteile zusammengefügt werden.

6. Produkt nach einem der vorhergehenden Ansprüche, das aus Kunststoffmaterial besteht und eine Dicke der inneren Wand (23) von ca. 1 - 2 mm und eine Dicke der äußeren Wand von ca. 1 - 2,5 mm aufweist. 5
7. Produkt nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** der Medikamenteninhalt eine Flüssigkeit ist, die ein Lösungsmittelvehikel enthält. 10
8. Produkt nach Anspruch 7, **dadurch gekennzeichnet, daß** das Lösungsmittelvehikel ein pharmazeutisch brauchbares Ölvehikel ist. 15
9. Produkt nach Anspruch 8 **dadurch gekennzeichnet, daß** das Ölvehikel ein Monoglycerid, Phospholipid oder ein Galactolipid ist.
10. Produkt nach Anspruch 9, **dadurch gekennzeichnet, daß** das Ölvehikel aus Glycerolmonooleat, Glycerolmonopalmitat und Glycerolmonostearat ausgewählt wird. 20
11. Produkt nach Anspruch 8, 9 oder 10, **dadurch gekennzeichnet, daß** es ein langkettiges Diglycerid enthält. 25
12. Produkt nach einem der Ansprüche 9 bis 10, das ein Fettsäuretriglycerid enthält. 30
13. Produkt nach Anspruch 12, **dadurch gekennzeichnet, daß** das Fettsäuretriglycerid Octansäure-/Decansäuretriglycerid (Tricaprylin) ist. 35
14. Produkt nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** das Medikamenteninhalt Calcium-Mupirocin, fraktioniertes Kokosnußöl, und Glycerolmonooleat ist. 40
15. Produkt nach einem der vorhergehenden Ansprüche, das ein Nasenspray-Behälter (21) ist, der mit Einrichtungen (29, 210) versehen ist, um seinen Medikamenteninhalt an den Nasenbereich eines Benutzers abzugeben. 45

Revendications

1. Article comprenant un conteneur à double paroi (21), comportant une paroi (22) de base et des parois latérales (23, 24) s'étendant vers le haut de la paroi (22) de base en direction d'une ouverture supérieure (25) d'embouchure du conteneur, et les parois latérales (23, 24) ont la forme d'une double paroi comprenant des parois espacées intérieure (23) et extérieure (24), constituées de matière plastique, une étiquette (28) étant située sur la surface exté-

rieure de la paroi extérieure (24), le corps (21) comportant une cavité intérieure (27) contenant un contenu médicamenteux et étant délimitée au moins en partie par la paroi intérieure (23), **caractérisé en ce que** la paroi (22) de base est une paroi (22) de base continue reliant les parois intérieure et extérieure (23, 24) et fermant l'espace (26) qui les sépare.

2. Article selon la revendication 1, **caractérisé en ce que** la cavité intérieure (27) est confinée directement par des parties de la paroi extérieure (24) et est en contact avec la paroi extérieure (24), mais **en ce que** l'étiquette (28) est appliquée à une partie de la paroi extérieure (24) dont la surface intérieure n'est pas en contact avec le contenu. 15
3. Article selon la revendication 1 ou 2, **caractérisé en ce que** les parois latérales (23, 24) ont la forme d'une double paroi continue (23, 24) s'étendant sur toute la hauteur de la cavité intérieure (27) de la paroi (22) de base à l'ouverture (25) d'embouchure. 20
4. Article selon l'une quelconque des revendications précédentes, **caractérisé par** des parois intérieure et extérieure sensiblement cylindriques (23, 24) qui sont sensiblement concentriques et coaxiales. 25
5. Article selon l'une quelconque des revendications précédentes, **caractérisé par** des parties de conteneur inférieure (21) et supérieure (212) qui s'assemblent avec un joint (213A, 213B) qui empêche une fuite ou une contamination du contenu, ces parties inférieure et supérieure (21, 212) de conteneur comprenant des parties de parois intérieures et extérieures inférieures (23, 24) et supérieures (23A, 24A) respectives du conteneur qui s'assemblent lorsque les parties supérieures (23A, 24A) et inférieures (23, 24) de conteneur sont emboîtées. 35
6. Article selon l'une quelconque des revendications précédentes, constitué de matière plastique, et comportant une paroi intérieure (23) d'environ 1 à 2 mm d'épaisseur, et une paroi extérieure d'environ 1 à 2,5 mm d'épaisseur. 40
7. Article selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le contenu médicamenteux est un fluide qui incorpore un véhicule de solvant. 45
8. Article selon la revendication 7, **caractérisé en ce que** le véhicule de solvant est un véhicule huileux acceptable du point de vue pharmaceutique.
9. Article selon la revendication 8, **caractérisé en ce que** le véhicule huileux est un monoglycéride, un phospholipide, ou un galactolipide.

10. Article selon la revendication 9, **caractérisé en ce que** le véhicule huileux est choisi à partir du glycérol mono-oléate, du glycérol monopalmitate et du glycérol monostéarate. 5
11. Article selon la revendication 8, 9 ou 10, **caractérisé par le fait qu'**il contient un diglycéride à chaîne longue.
12. Article selon l'une quelconque des revendications 8 à 10, contenant un triglycéride d'acide gras. 10
13. Article selon la revendication 12, **caractérisé en ce que** le triglycéride d'acide gras est un triglycéride caprylique / caprique (Tricapryline). 15
14. Article selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le contenu médicamenteux comprend de la mupirocine de calcium, de l'huile de noix de coco fractionnée et du glycérol mono-oléate. 20
15. Article selon l'une quelconque des revendications précédentes, dans lequel l'article est un conteneur (21) pour pulvérisation nasale équipé de moyens (29, 210) servant à délivrer son contenu médicamenteux à la région nasale d'un utilisateur. 25

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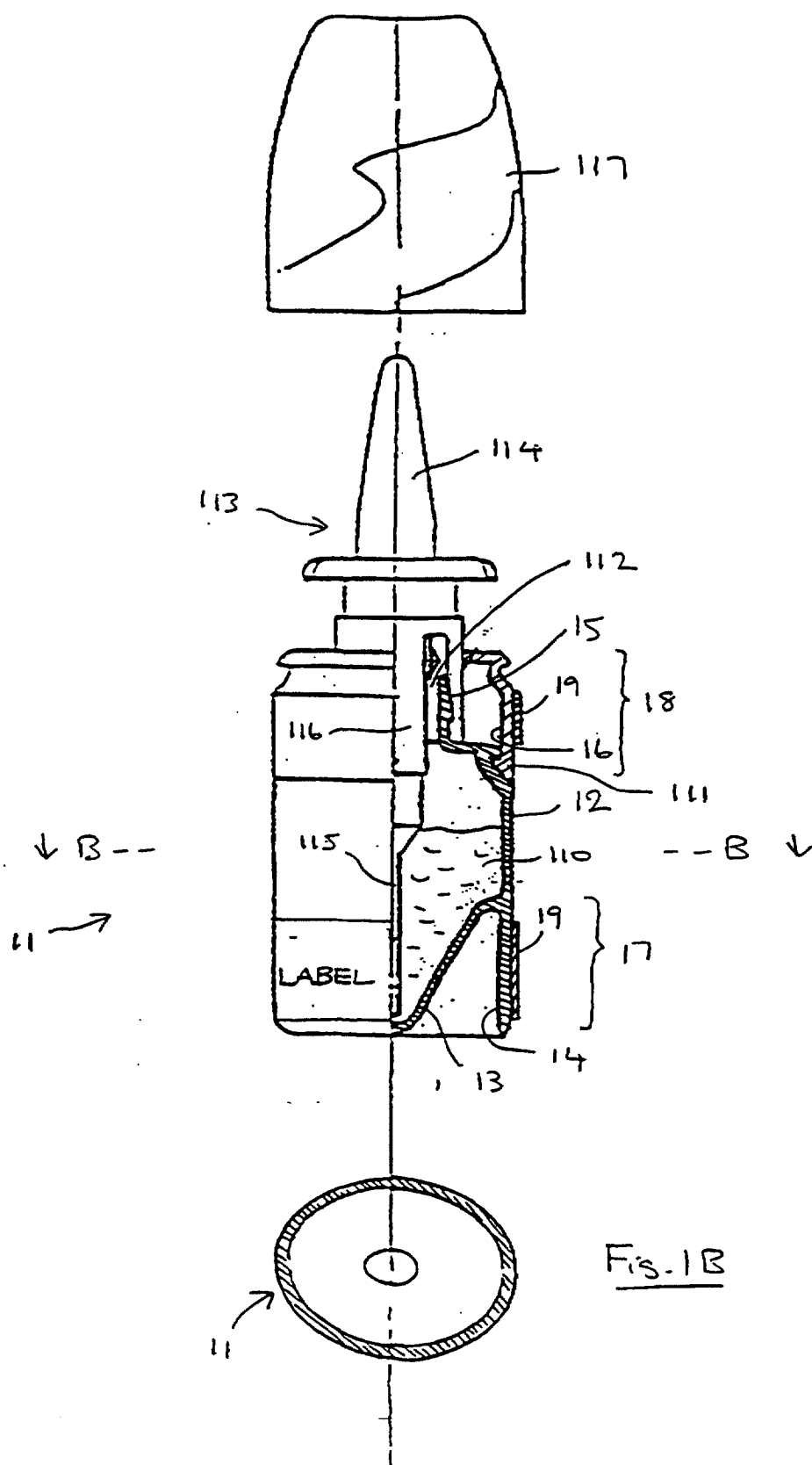
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Fig. 1



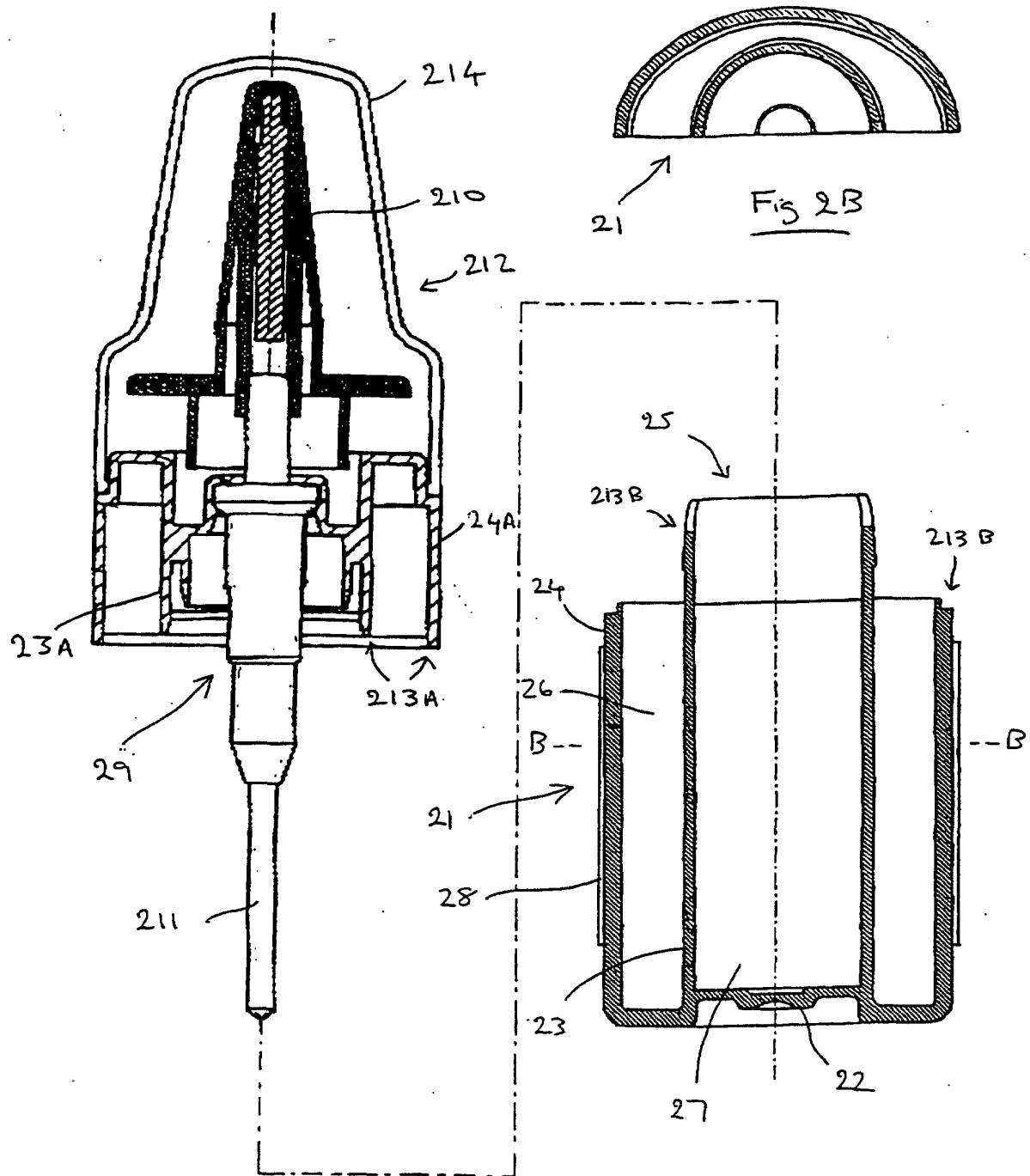


Fig. 2