

Container

The invention relates to a container, in particular a plastic ampoule which is produced using a blow molding process, and which is filled and closed in the production mold, said container having a sleeve-type neck part connected to a container body as an axial extension, said neck part forming a seat for a pre-formed insert extending along the axis of the neck part, and said neck part being formed in the production mold, on a peripheral region of the insert. Moreover, the invention relates to a method, which is provided in particular for producing such a container.

Containers of this type, in which the container body is made of a thermoplastic material such as low-density or high-density polypropylene, polyethylene or similar materials that are compatible with the intended container contents, are known, cf. WO 2008/098602 A1. Such containers, for example, produced by the known bottelpack® method are usually used for receiving and delivering fluids for therapeutic or cosmetic purposes, the liquid being delivered via the insert seated in the neck part of the container body. Its exit or delivery end is preformed in accordance with the intended use. As shown in the document mentioned above, in this respect, for example, an exit forming a dropper can be provided for the direct delivery of drops, for instance eye drops, wherein the dropper opening can be uncovered by unscrewing a container closure cap. For delivery via an injection needle, a port for an injection needle or a plastic mandrel can be provided at the delivery region of the insert, wherein a perforation region that can be pierced by a mandrel or an injection needle may be formed at the insert. Regardless of the specific design of the delivery region, it may be covered by an end cap or closure cap that is removed from the insert before the contents of the container are used.

For safety reasons in the use of such containers, it is decisive that in the integral molding of the neck part to the adjoining peripheral region of the insert in the manufacturing mold, said insert is securely fixed in the seat of the neck part in such a way that, even in case of stress applied to the delivery region of the insert during use, the seal between the seat and the insert is not adversely affected and thus leakage, an increased permeation or a microbiological contamination of the container contents can be safely ruled out.

With regard to this problem, the invention addresses the problem of providing a container of the considered type in which a secure seal between the neck part of the container and the insert is ensured and which can be used in particular for medical, cosmetic or industrial purposes, but also for beverages or foods, suitable filling materials being liquids, suspensions, emulsions, ointments, creams or gels.

According to the invention, this object is achieved by a container having the features of Claim 1 in its entirety.

According to the characterizing part of claim 1, one essential feature of the invention is that at least one sealing element is provided on the insert, said sealing element forming a seal in a sealing region surrounding the axis in combination with a contact surface formed on the seat of the neck part. If a sealing element is provided on the insert, the process of molding the wall parts of the neck part forming the seat for the insert can be designed in such a manner that a particularly reliable sealing connection is formed in the seat.

In a particularly advantageous way, the sealing element can be formed by a molded part of the insert. The container according to the invention can be manufactured in a particularly simple, efficient and cost-effective manner for the sealing element formed by a part of the insert itself, resulting in a corresponding reduction in the expenditure for providing a separate sealing element.

In particularly advantageous exemplary embodiments of the invention, the arrangement is such that the molded part forming the sealing element adjoins the end of the peripheral region facing the contact surface of the seat, at which

peripheral region the neck part is formed onto the insert. This can be realized in a particularly simple manner using an axial seal between the seat and the insert.

In a particularly advantageous way, the sealing element can be formed by the rim of a ring formed on the insert, said rim facing the contact surface at the seat of the neck part, wherein the ring can advantageously have the form of an axially protruding rib. In order to ensure particularly reliable sealing, the rib can have a shape tapering towards the rim adjoining the contact surface, to achieve a good sealing effect in relatively narrow, defined sealing region.

In particularly advantageous exemplary embodiments at least one axially protruding structural part is provided on the insert, displaced radially from the ring toward the interior, extending beyond it, toward the container body. Because the narrowed collar part formed between the neck part and the container body contacts the inner wall, a support of the insert relative to cross forces acting thereon during use is formed. The structural part can advantageously have the shape of a coaxial truncated cone tapering in the direction of the container body, having a concentric passage in the manner of a bore, opening towards the container body. In doing so, the external conical shape of the structural part may cling to the shape of the funnel-like collar part of the container body.

Alternatively, the arrangement can be such that the insert forms a hollow cylinder within the peripheral region, on the inside wall of which a plurality of axially protruding structural parts are provided in the form of wings, whose free end regions adjoin the inside of the collar part.

In advantageous exemplary embodiments, a hollow syringe cone is connected to the end of the peripheral region of the insert facing away from container body, the cavity of said syringe cone is flush with the cylindrical passage of the truncated cone, from which it is separated by a web, which forms a wall part that can be perforated for extraction purposes, which can for instance be pierced by a hollow plastic mandrel, a double-ended cannula, similar to DIN EN ISO 7885 or DIN 13097-5, or double-pointed injection needles, such as are used for the administration of insulin.

In further advantageous exemplary embodiments, a lockable connection part, having a 6° outer cone (Luer) and a fixedly connected female threaded part in accordance with EN 1707:1996 and sealed by a cap, is connected to the peripheral region of the insert facing away from the container body.

In further advantageous exemplary embodiments, a lockable connection part having an outer cone with a closed tip and a firmly connected female threaded part, similar to EN 1707:1996, that is opened by breaking or twisting the tip off, is connected to the peripheral region of the insert facing away from the container body.

To secure the insert in the seat by means of integral molding the neck part to the peripheral region of the insert, to ensure extra protection against both axial forces and against torques, surface irregularities can advantageously be formed on the peripheral region of the insert, separated from one another by radially recessed surface sections. This results in a kind of positive locking between the insert and the neck part of the container body when it is molded thereto.

In the manner known *per se* for such containers, a closure cap, enclosing the syringe cone or any other differently shaped extraction area forming a predetermined breaking point to enable the detachment from the neck part, can be formed to the end of the neck part facing away from the container body. If the insert is secured against acting torques by a positive locking, the cap can be separated in a convenient and secure way by twisting at the predetermined breaking point, wherein a rotary knob to facilitate a manual twist-off can be integrally formed on the closure cap, for instance.

The object of the invention is also a method, which is provided in particular for manufacturing a container according to one of claims 1 to 16 and which has the features of patent claim 17.

Below the invention is explained in detail using exemplary embodiments shown in the drawing.

In the drawings:

- Fig. 1 shows the front view of an exemplary embodiment of the inventive container approximately enlarged by factor of 3 in relation to a practical embodiment;
- Fig. 2 shows a longitudinal section of the exemplary embodiment, rotated by 90° in relation to Fig. 1;
- Figs. 3 and 4 show a perspective oblique view or a longitudinal section of the insert body of the exemplary embodiment of the container, magnified approximately 2.5-times in relation to Figures 1 and 2;
- Figs. 5 and 6 show the insert for a modified exemplary embodiment of the container corresponding to the representations of Figs. 3 and 4;
- Figs. 7 and 8 show the insert body for a further modified exemplary embodiment of the container corresponding to the representations of Figs. 3 and 4;
- Figs. 9 and 10 show a perspective oblique view or a longitudinal section of the insert for a further modified exemplary embodiment, as compared to Figs. 3 or 4 even more magnified and illustrated broken-off;
- Fig. 11 shows a broken-off, perspective oblique view of an insert for a still further modified exemplary embodiment, drawn in the scale of Figs. 9 and 10;
- Fig. 12 shows the insert of Fig. 11 in a position mounted on the neck part of the associated container, in a broken-off and cut representation;
- Fig. 13 a perspective oblique view of an exemplary embodiment of the

container in the form of a small-volume bottle;

- Fig. 14 shows a truncated longitudinal section of the exemplary embodiment of Fig. 13, wherein only the range of neck part and the closure cap is depicted;
- Fig. 15 shows a longitudinal section of the insert of the exemplary embodiment of Fig. 8 and a heating device depicted as a diagram, wherein the state before insertion into the heating device is shown;
- Fig. 16 shows a representation corresponding to Fig. 15 with the insert inserted into the heating device;
- Fig. 17 shows a longitudinal section of the insert in the state after heating in the heating device;
- Fig. 18 shows a greatly simplified longitudinal section of the blow-molding device for manufacturing a container according to the invention, wherein a step of the manufacturing process before the insertion of heated insert is shown;
- Fig. 19 shows the production step in which the head jaws of the blow-molding device from Fig. 18 are closed, and
- Fig. 20 shows a schematically simplified longitudinal section of the container taken from the blow-molding device.

The invention is described in reference to the drawings, based on exemplary embodiments, in which a container body 2 has a neck part 4, which forms a seat 6 for an insert 8, for the delivery of the liquid pre-stored in the container body 2 when the container is used. In the examples shown, the container body 2 has the shape of a collapsible ampoule having a cross-section shaped approximately like a rhombus.

The container body 2 made of plastic material by blow molding is designed, at a total volume of 2 ml, for a filling volume of 1.5 ml and has a collar part 10, forming, as a local restriction, the transition to the sleeve-like neck part 4 having a larger diameter. In doing so, the collar part 10 has the shape of a funnel, to which, coaxially to a container axis 12, the neck part 4 is connected in the form of a circular cylindrical sleeve, concentric to the axis 12.

The insert 8, which is separately shown in Figs. 3 and 4, has the shape of an integrally formed rotary body made of plastic, concentric to the axis 12, wherein preferably the same material, or a material of the same class of materials, from which the container body 2, including the collar part 10 and neck part 4, is made, may be provided. In the manufacturing process according to the bottelpack® method, where a plastic tube is extruded into a blow mold; in which the container body 2 including the collar part 10 is formed using main mold jaws and the adjoining container parts, like the neck part and optionally an adjoining cap, are formed using head jaws, the insert 8 is inserted into the seat 6 of the neck part 4 before the head jaws are closed. The subsequent closing of the head jaws, as is usual in the prior art, is used to form the neck part 4 to the associated peripheral region 14 (cf. Fig. 3 and 4) of the insert 8. In the example shown in Figs. 1 and 2, a closure cap 16 is formed to the end of the sleeve part 4, wherein a predetermined breaking point 18 is formed at the transition as a detachable separation point.

As can be seen in Figs. 3 and 4, the insert 8 has a main part 22, to which the peripheral region 14 is formed, to which the neck part 4 is formed during the closing of the head jaws. In the performance of the mentioned bottelpack® process, this is done after the container contents have been filled into container body 2 by means of a filling mandrel. Deviating from the form of a smooth cylinder jacket, the main part 22 shows surface irregularities at the peripheral region 14, which are formed by radially recessed surface areas 26 next to un-recessed surface areas 24. In the example of Figs. 3 and 4, the recessed surface areas 26 are formed by circumferential grooves in the manner of annular grooves extending in the circumferential direction, i.e. the un-recessed surface areas 24 are shaped like annular ribs extending at an axial distance to one another. In this shaping of the

peripheral region 14, a kind of serration is created when the neck part 4 is molded to the main part 22 of the insert 8, to secure the insert 8 in the seat 6 of the sleeve part 4 using the formed positive lock against any acting axial forces. A syringe cone 28 is formed on the end of the main part 22 of the insert 8 facing away from the seat 6, which forms the delivery end of the insert 8. In the example shown, the syringe cone 28 has an axial length that is greater than the length of the main part 22, and has an inner, coaxial cavity 30, which is closed at the end adjoining the main part 22 by a cross web 32, in which a central, recessed part 34 is formed. A coaxial bore-like passage 36, which is open at the end of the insert 8 facing the container body 2, is connected to the web 32. The recessed area 34 forms a region of reduced wall thickness in the web 32, which serves as perforation area for a hollow plastic mandrel, a double-ended cannula during extraction, similar to DIN EN ISO 7885 or DIN 13097-5, to extract container contents through the passage 36.

A step 38 is formed in seat 6 of the neck part 4 at the transition to the collar part 10 (cf. Fig. 2), which serves as a contact surface for a sealing element, which seals the insert 8 in the seat 6. The sealing element is formed by a molded part of the insert 8 itself. As can be best seen in Fig. 4, a ring 42 is formed on the end of the peripheral region 14 facing the container body 2 along the peripheral rim, to which an axial recess 44 is connected radially inwards in the form of an annular groove, i.e. the ring 42 forms an axially protruding annular rib. It is tapered, as Fig. 4 clearly shows, towards the axially protruding rim, with which it adjoins the contact surface at the step 38 of the seat 6, the tapered rib shape of the ring 42 forming an effective, narrow sealing region.

Radially inwardly from the recess 44, a coaxial truncated cone 46, at the end of which the bore 36 is open, tapering toward the container body 2, adjoins the main part 22. As shown in Fig. 2, in the inserted position the outer conical surface of the truncated cone 46 adjoins the inside of the funnel-like collar part 10, the truncated cone 46 forming a structural part centering the insert 8 in the seat 6 and supporting it against transverse forces.

Figs. 5 and 6 show a modified exemplary embodiment, which differs from the example described above, only by a modified shape of the surface irregularities on the peripheral region 14 of the main part 22 of the insert 8. Instead of the recessed surface areas 26, which extend only in the circumferential direction, in the example of Fig. 5 and 6, the recessed surface areas 26 extend both in the circumferential direction and in the axial direction, so that rib parts 52, and not closed annular ribs, are formed at the peripheral region.

Figs. 7 and 8 show an exemplary embodiment with a further modified configuration of the peripheral region 14 on the insert 8, which corresponds to the examples described above, concerning the configuration of the sealing element in the form of a ring 42. As shown in Figs. 7 and 8, a radially protruding annular body 54 having a rounded, bead-like shape, from which a crown of circumferentially distributed longitudinal ribs 56 extends in the direction of the syringe tip 28, is provided in approximately the central longitudinal section of the main part 22, wherein the longitudinal ribs 56, however, terminate at a distance in front of the syringe cone 28. The outside of the longitudinal ribs 56 has a rounded shape, as shown in Fig. 7. In this configuration, having surface irregularities at the peripheral region 14, a positive locking is formed between the neck part 4 and the insert 8 formed thereto, which secures the insert 8, both by means of the longitudinal ribs 56 against rotation, and using the annular body 54, against axial movement.

Figs. 9 and 10 show an example still further modified, in which a crown of longitudinal grooves 58 distributed around the periphery is disposed at the peripheral region 14 of the insert 8. Further, as shown in Fig. 10, the passage 36, extending in the truncated cone 46 and the cavity 30, extending towards the delivery end, are not separated by a radially extending transverse web 32, but an inner cone 62 extends from the truncated cone 46 into the cavity 30. The inner cone 62 is also shaped like a truncated cone, which is closed at the end located in the cavity 30 by a sort of diaphragm 64, which forms the perforation region.

Figs. 11 and 12 show an exemplary embodiment in which the insert 8 forms a hollow cylinder 66 inside the peripheral region 14, the rim of which, facing the container

body 2, forms a ring 68 having a curved surface as a sealing element, adjoining the contact surface at the seat 6 of the neck part 4 formed by the step 38 in a sealing manner. On the outside of the hollow cylinder 66, longitudinal ribs 72, which end at a short axial distance in front of the sealing element forming ring 68, are designed as surface irregularities distributed on the circumference. Axially protruding structural parts in the form of circumferentially distributed wings 74 are formed on the inside of the hollow cylinder 66, which extend in radial planes, and the free end parts 76 of which contact the inside of the collar part 10 at the mounting position and thus ensure a good axial centering in the seat 6 even for inserts 8 having larger diameters.

For easy detachment of the over-mold closure cap 16 at the predetermined breaking point 18, a rotary knob having laterally projecting handle parts 82, 84 is formed at the end part of the closure cap 16, as shown in Fig. 1.

The respective sealing element can apply the individually required sealing effect due to its being inherently stable; but it is also possible to melt the sealing element 42, 68, which then forms a solid, fluid-impermeable barrier to the other adjacent plastic material, by thermal input. Possibly resulting excess plastic material from the melting process can be displaced into the hollow groove 44 (cf. Fig. 4) and there serve as an additional filler material for welding, to achieve a homogeneous welded joint in this way.

Figs. 13 and 14 show an alternative embodiment of the container in the form of a small volume vial, intended for a capacity of about 30ml, in which the container body 2 is formed by a bellows, which can be compressed during an extraction process. As Fig. 14 shows, the insert 8, which is inserted as an insert part in the sleeve part 4, has an extraction cone in the form of a male Luer Lock 90. It extends coaxially within a sleeve part 89, the outside of which constitutes the peripheral part, to which the neck part 14 is formed. The Luer Lock 90 protruding beyond the end of the sleeve part 89 has a closure part 92 for closing its outlet opening, which is formed to the Luer Lock 90 over a predetermined breaking point 91. The closure part 92 has an axially protruding bar element 93, which is tightly enclosed by the overmold closure cap 16. In this way, a rigid connection is created, i.e. the closure part 92 can be

safely taken off by means of releasing the predetermined breaking point 91 and the separation point 18 together with the overmold closure cap 16 by twisting off the latter using the rotary levers 82, 84 integrally formed thereon.

Figs. 15 to 17 illustrate steps of the method according to the invention which enable a particularly high anti-microbial sealing effect to be obtained between the insert 8 and the container body 2 during manufacture of the container. In this respect, the procedure is such that the insert 8, in particular in the area of the ring 42 forming the sealing element, is heated to a temperature of at least 50° to 70° Celsius before the insertion into the seat 6 of the neck part 4 during the manufacture of the container according to the bottelpack® process. In this way, the formation of the fusion bond during the closing of the head jaws 97 (Figs. 18 to 20) is facilitated. Figs. 15 to 17 illustrate the procedure. Immediately prior to insertion into the blow-molding device, the insert 8 is preheated by a heating device, which in Figs. 15 and 16 is designed as a so-called heat reflector 94. Fig. 15 shows the state before contact with the heat reflector 94, while Fig. 16 illustrates the heating process. Preheating can be done by direct contact of the sealing element 42; 68 using a heated surface or by radiating heat, for instance using infrared rays or laser beams, or, if the insert 8 is made from correspondingly additized plastics, also by inductive coupling of an electromagnetic field. To promote the formation of the fusion bond, the insert 8 also can be composed of several different materials, e.g. produced by multicomponent injection molding. The sealing element 42; 68, for instance, may be formed from a thermoplastic polymer softening at low temperatures and having good adhesion properties to the polymer material of the container body 2, in particular a thermoplastic elastomer can be provided (TPE) for this purpose. The other parts of the insert 8 can be made of polymers having higher softening temperatures. In this way, a high dimensional stability of the insert 8 is ensured as well as a tight connection by melting, even at warming to higher temperatures. To achieve a particularly high microbiological tightness after being subjected to mechanical torsional stress, it is advantageous if the sealing element 42 is located outside the area of the circumferential surface irregularities 24, 26; 52; 54; 56; 58; 72 located on the insert 8, to prevent the torsional moments/forces, for instance during opening, from significantly affecting the sealing element 42.

Figs. 18 to 20 show the manufacturing steps downstream of the heating process. Figure 18 shows the insert 8 immediately before the insertion procedure. During the insertion, at first merely an axial pressure force is applied to the insert 8, to ensure a fusion bond, upon which radial forces are applied after a time delay by closing the head jaws 97, to achieve the interlocking between the surface irregularities of the peripheral region of the insert 8. A short delay of even less than one second between these operations has a particularly advantageous effect. Fig. 19 shows the state after the head jaws 97 have been closed, wherein the over-mold closure cap 16 is formed and sealed to produce the closed state of the container as shown in Fig. 20.

For the process of heating, the following temperature ranges have proven useful if suitable materials were used for the tube 98 forming the container and the insert 8 with sealing element 42; 68:

Container	Material: Insert/Sealing Element	Temperature Sealing
LDPE	LDPE/LDPE	up to 95-120°C
LDPE	HDPE/HDPE	up to 130-145°C
PP	PP/PP	up to 150-170°C
PET	PET/PET (amorphous)	up to 70-100°C
PP	PP/TPE	up to 120-160°C

C l a i m s

1. A container, in particular a plastic ampoule, which is produced using a blow molding process, and which is filled and closed in the production mold, said container having a sleeve-type neck part (4) connected to a container body (2) as an axial extension, said neck part forming a seat (6) for a pre-formed insert (8) extending along the axis (12) of the neck part (4), and said neck part being formed in the production mold, on a peripheral region (14) of the insert (8), characterized in that at least one sealing element (42; 68) is provided on the insert (8), said sealing element forming a seal in a sealing region surrounding the axis (12), in combination with a contact surface (38) formed on the seat (6) of the neck part (4).
2. The container according to claim 1, characterized in that the sealing element (42; 68) is formed by a molded part of the insert (8) associated with the latter.
3. The container according to claim 1 or 2, characterized in that the sealing element (42; 68) adjoins the end of the peripheral region (14), on which the neck part (4) to the insert (8) is formed, facing the contact surface (38) of the seat (6).
4. The container according to one of the preceding claims, characterized in that the sealing element (42; 68) is formed by the edge of a ring (42; 68) formed on the insert (8) facing the contact surface (38) on the seat (6) of the neck part (4).
5. The container according to one of the preceding claims, characterized in that the ring-shaped sealing element (42) has the form of an axially protruding rib.
6. The container according to one of the preceding claims, characterized in that the sealing element (42) is rib-shaped and has a shape tapering towards the rim adjoining the bearing surface (38).

7. The container according to one of the preceding claims, characterized in that at least one axially protruding structural part (46; 74) is provided on the insert (8) extending offset radially inwards to the annular sealing element (42; 68) and beyond the former towards the container body (2).
8. The container according to one of the preceding claims, characterized in that the axially protruding structural part has the shape of a coaxial truncated cone (46) tapering in the direction of the container body (2), which has a concentric passage (36) that is open towards the container body (2).
9. The container according to one of the preceding claims, characterized in that the insert (8) forms a hollow cylinder (66) within the peripheral region (14), on the inner wall of which a plurality of axially protruding structure parts in the form of circumferentially arranged distributed wings (74) are provided, the free end regions (76) of which contact the inside of the collar part (10).
10. The container according to one of the preceding claims, characterized in that a hollow syringe cone (28) is connected at the end of the peripheral region (14) of the insert (8) facing away from the container body (2), the cavity (30) of which is flush with the bore-like passage (36) of the truncated cone (46), from which it is separated by a web (32) forming a wall part (34) that can be pierced for an extraction process.
11. The container according to one of the preceding claims, characterized in that there are surface irregularities (24, 26; 52; 54; 56; 58; 72) at the peripheral region (14) of the insert (8), which are formed by surface parts separated from each other by radially recessed or raised surface areas and arranged axially offset to the annular sealing element (42) towards the cone (28).
12. The container according to one of the preceding claims, characterized in that an over-mold closure cap (16) enclosing the syringe cone (28) is formed to the end of the neck part (4) facing away from the container body (2) forming a predetermined breaking point (18) enabling the separation from the neck part (4).

13. The container according to one of the preceding claims, characterized in that an integral, male Luer Lock (40) is formed on the insert (8), said Luer Lock having a closure part (92) connected to the over-mold closure cap (16) and when it is removed, can be removed together with the latter at a separation point (91) at the end of the Luer Lock (90), for opening the cone at the upper end of its cone (28).
14. The container according to one of the preceding claims, characterized in that the closure part (92) comprises a bar (93) extending axially away from the cone (28), integrated in the region of the handle parts (82, 84) serving as a turn-off knob in the over-mold closure cap (16).
15. The container according to one of the preceding claims, characterized in that the insert (8) is formed of at least two different materials, of which at least one is softenable at low temperatures.
16. The container according to one of the preceding claims, characterized in that the softenable material is a thermoplastic polymer having good adhesion properties to the polymer material of the container body, in particular a thermoplastic elastomer (TPE), and that there is another polymeric material having a higher softening temperature.
17. A method, which is provided in particular for the manufacture of a container according to one of claims 1 to 16, characterized in that the sealing element (42; 68) of the insert (8) is energetically treated, in particular heated, before its insertion into the blow-molding device (97, 99).
18. The method according to claim 17, characterized in that the operation of inserting the insert (8) in the blow-molding device (97, 99) is performed such that at first only an axial pressure force is applied, to ensure a fusion bond of the sealing element (42; 68) on the seat (6) of the neck part (4), and that then, delayed, radial forces are applied by closing of the head jaws (97) to achieve the serration of the surface irregularities (24, 26; 52; 54; 56; 58; 72) of the peripheral region (14).