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(71) Applicant : **AUTOMATIC LIQUID PACKAGING, INC.**
2200 West Lake Shore Drive
Woodstock Illinois 60098 (US)

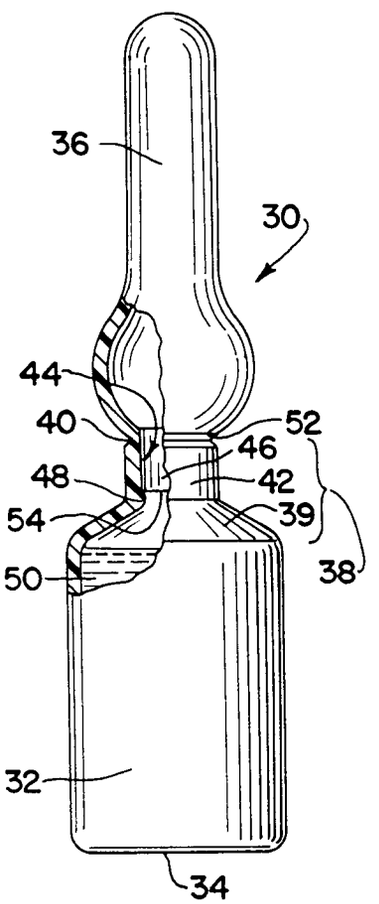
(72) Inventor : **Weiler, Gerhard H.**
54 Watergate
South Barrington, Illinois 60010 (US)

(74) Representative : **Fisher, Adrian John**
CARPMAELS & RANSFORD 43 Bloomsbury Square
London WC1A 2RA (GB)

(54) Hermetically sealed vial.

(57) A hermetically sealed thermoplastic container (30) such as an ampoule or a vial is provided with an internal receptacle (42,44) that receives a portion of a syringe tip in a press-fit relationship. The receptacle (42,44) includes a circumferential shoulder (48) against which the inserted syringe tip abuts. The container (30) can be made by a form-fill-seal technique.

Fig. 2



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Technical Field

This invention relates to hermetically sealed, filled thermoplastic containers from which the container contents can be withdrawn with a syringe.

Background of the Invention

Filled and hermetically sealed containers of a thermoplastic material, usually a polyolefin, are well known in the art. Such containers can be readily made utilizing a form-fill-seal technique by means of which a container is molded, filled, and sealed in a single continuous operation. This technique is described and illustrated in U.S. Patent No. 4,671,763 to Weiler.

One application of the form-fill-seal technique is in the production of unit dose containers such as ampoules and vials the contents of which can be withdrawn for use by means of a syringe. One such ampoule is illustrated in Figure 8 of the aforementioned U.S. Patent No. 4,671,763 to Weiler. Another type of unit dose vial is shown in U.S. Patent No. 4,643,309 to Evers.

While a syringe can be used in conjunction with both of the foregoing types of containers, each type exhibits certain shortcomings. In particular, the ampoule shown in U.S. Patent No. 4,671,763 to Weiler usually requires a substantial container wall thickness for engagement with a syringe tip. This is not always practical. The unit dose container shown in U.S. Patent No. 4,643,309 to Evers, on the other hand, requires closely controlled conicity of a relatively long neck portion for suitable seating of the conical tip of a syringe substantially in its entirety. Such requirements undesirably contribute to the overall cost of the container.

It has now been found, however, that the shortcomings of both of the aforementioned container designs can be obviated, or at least mitigated to a relatively large extent, by providing instead a press-fit receptacle in the container neck portion for receiving but a distal portion of the syringe tip. The present design provides the further advantage that once the syringe tip has been received in a press-fit relationship into the container neck portion, the resulting syringe-container assembly is not likely to separate from one another prematurely even with relatively rough interim handling.

Summary of the Invention

The present invention is directed to a filled, hermetically sealed thermoplastic container suitable as a unit dose container for medication that is to be administered by a syringe.

A container embodying this invention can be readily made by the well-known form-fill-seal technique and includes a hollow body portion that is closed at one end and terminates at the other end in an elongated neck portion provided with a press-fit receptacle for a syringe tip. The receptacle includes a circumferential shoulder against which the inserted syringe tip abuts when the container contents is to be withdrawn by the syringe.

The neck portion is also provided with a closure that is unitary therewith. This closure is joined to the neck portion by a frangible web situated in a groove about the neck portion.

Other features of the present containers will be apparent from the accompanying detailed description and the drawing.

Brief Description of the Drawing

In the drawing,

FIGURE 1 is a side elevational view, partly broken away to show interior detail, of an ampoule disclosed in commonly-owned U.S. Patent No. 4,671,763;

FIGURE 2 is a side elevational view, also partly broken away to show interior detail, of an ampoule embodying the present invention;

FIGURE 3 is a side elevational view of a thermoplastic unit dose container embodying the present invention and provided with a tab for facilitating closure removal so as to expose an internal press-fit receptacle for a syringe tip; and

FIGURE 4 is an enlarged fragmentary sectional view of the neck region of a container embodying the present invention during the molding of that region.

Description of Preferred Embodiments

While this invention is susceptible of embodiment in different forms, two such forms are described in detail hereinbelow as specific embodiments. The precise shapes and sizes of the described containers are not essential to the invention unless expressly so indicated.

Containers embodying the present invention can be manufactured and filled with a desired contents utilizing the form-fill-seal technique described in detail in U.S. Patent No. 4,671,763 to Weiler, which patent is commonly owned. The disclosure of said U.S. Patent No. 4,671,763 is incorporated herein by reference to the extent pertinent.

In general, the manufacture includes the extrusion of a thermoplastic material such as a polyolefin, e.g., low density polyethylene, high density polyethylene, polypropylene, or the like, as a length or segment of a parison in the form of a vertically oriented, elongated, hollow, semi-soft tube between a pair of main mold halves. The container body is initially formed from this parison with an open top. Means are provided for maintaining the opening at the top of the

parison segment in the portion of the parison extending upwardly above the main mold means.

An extendable and retractable blowing assembly with a sealing/forming mandrel and blowing/filling nozzle is positioned into the length of parison in the main mold halves to temporarily seal the opening. A gas is injected into the parison to mold the container body, with or without vacuum assist, in the mold cavity defined by the main mold halves. The resulting molded container body is then filled with the desired liquid contents and subsequently sealed.

The main mold halves, along with the cooperating sealing mandrel on the blowing assembly, define a structure for molding the frangible web structure as well as a press-fit receptacle for a syringe tip.

Sealing mold halves, located above the main mold halves, are subsequently closed to pinch the parison and seal the formed and filled container.

Each of the main mold parts is provided with a protuberance of substantially cuneiform, i.e., wedge-shaped, cross-section that extends into the mold cavity to form a continuous circumferential ridge with a peak. A portion of the semi-soft thermoplastic material is pressed against the ridge to form a peripheral frangible web having a controlled thickness less than the container wall thickness while providing an effective seal within the main mold to permit the shaping of the container body portion by pressurization from within. The semi-soft material that constitutes the extruded parison segment is caused to flow across the peak of the circumferential ridge during the pressing. The containers embodying the present invention include a seamless, smooth peripheral band inside the neck portion of the container that is unitary with the frangible web and defines the inside surface thereof. This smooth peripheral band terminates in a circumferential shoulder and together with this shoulder defines a press-fit receptacle for the syringe tip.

Thus, the apparatus for making the present container includes (1) main mold means defining a mold cavity for initially forming from an extruded length of a parison the container body with an open top, (2) means for maintaining an opening at the top portion of the parison that extends upwardly from the main mold means, (3) an extendable and retractable temporary sealing/forming assembly that includes means for temporarily sealing the top opening and for forming a peripheral frangible web and the press-fit receptacle in the container neck portion below the top opening (i.e., in the sealed portion of the formed container) in cooperation with the main mold means, and (4) sealing mold means operable upon the upwardly extending portion of the parison above the formed frangible web for permanently sealing the top of the formed container after the temporary sealing assembly is retracted.

The ampoule described in the aforementioned U.S. Patent No. 4,671,763 is shown in FIGURE 1. Ampoule 10 has a body portion 12, bottom portion 14, tip 16, and a reduced diameter neck portion 18 that joins tip 16 to body portion 12. Neck portion 18 and tip 16 are joined to one another by unitary frangible web 20 situated therebetween.

In contradistinction, an ampoule embodying the present invention is shown in FIGURE 2. Specifically, ampoule 30 is provided with neck portion 38, which, while unitary with hollow container body 32, includes an upstanding boss 42 that defines an elastically deformable receptacle 44 for receiving therewithin a portion of a syringe tip, and a downwardly extending skirt portion 39 from boss 42 that connects to body portion 32. Receptacle 44 includes a seamless band or inside wall 46 and inwardly extending circumferential shoulder 48 against which a syringe tip usually abuts when in a press-fit relationship with seamless band 46.

Tip 36 provides a unitary closure for neck portion 38 and thus container body 32 filled with a desired liquid contents 50. Container bottom 34 is a substantially flat surface that can support the ampoule 30 in an upright position after it has been opened by breaking off tip 36.

A unitary but severable juncture of tip 36 to container neck portion 38 is provided by frangible web 40 between tip 36 and hollow boss 42 in neck portion 38.

Frangible web 40 is situated in external circumferential groove 52 provided about container neck portion 38. When tip 36 is to be severed from the rest of the unitary container or ampoule 30 so as to gain access to the liquid contents 50 thereof, tip 36 is twisted or bent to one side whereupon tip 36 parts from neck portion 38, and from boss 42 in particular. Preferably, frangible web 40 and associated groove 52 that circumscribes neck portion 38 are situated so that any burrs or rough remnants of web 40 after severance do not interfere with the receipt of a syringe tip into receptacle 44 in a press-fit engagement therewith.

As mentioned hereinabove, a portion of a syringe tip is received in receptacle 44 and abuts shoulder 48. Thus, sufficient axial force can be applied while urging the syringe tip into a press-fit relationship with receptacle 44 without concern that the syringe tip may be inadvertently pushed through the container neck portion and into the container body portion. Also, in this manner a liquid pooling region 54 is provided in container neck portion 38 to maximize the amount of liquid that can be withdrawn from ampoule 30 while a syringe tip is inserted into receptacle 44 and the ampoule inverted.

Receptacle 44 is sized so as to receive at least the distal end of the nozzle of a contents-withdrawing implement, e.g., a syringe tip, in a press-fit (or interference-fit) relationship. That is, the inside diameter of receptacle 44 is such that band 46 of boss 42 is elastically distorted and applies pressure on the nozzle tip

received therewithin which pressure is sufficient to hold together the nozzle tip and container neck 38 while container contents 50 is withdrawn. Stated in another way, the minimum permissible difference between the dimensions of the male nozzle part and the female receptacle part, i.e., the allowance, has a negative value so that the elasticity of the container material can be utilized to grasp and hold the inserted portion of the syringe tip.

The depth-to-width ratio of receptacle 44, when exposed, can vary, but preferably is no more than about 1, more preferably in the range of about 0.6 to about 0.8. The receptacle inside diameter along the longitudinal axis of receptacle 44 is substantially the same, there being but a small taper toward the container body portion as needed for the convenient withdrawal of the mandrel-carrying nozzle after the receptacle has been molded during container manufacture.

Another unit dose container embodying the present invention is shown in FIGURE 3 where vial 60 is provided with neck portion 68 equipped with an internal syringe tip receptacle in elastic boss 72 of neck portion 68. The configuration and dimensions of the receptacle defined within neck portion 68 are substantially the same as those shown in FIGURE 2.

Vial 60 includes hollow body portion 62 closed at bottom end 64 and opening into the neck portion 68 that includes the aforementioned boss 72 and the therein defined elastically deformable receptacle. Unitary, oblate bottom tab 65 extends longitudinally from bottom end 64 and is suitable for inscription of lot indicia 67, expiration dates, or like purposes. Bottom tab 65 also facilitates the handling of container 60 in instances where the unit dose contained therein is relatively small and the vial itself is sized commensurately.

Container closure for vial 60 is provided by cap 66 unitary with neck portion 68 and joined thereto by unitary frangible web 70 in groove 82. To facilitate the removal of cap 66 from neck portion 68, grip tab 68 is provided unitary with cap 66.

The molding of the nozzle or syringe tip receiving receptacle in containers embodying the present invention is illustrated in FIGURE 4 which shows a container neck portion 98 with boss 102 and skirt 105 within main mold parts 120 and 122 that surround parison segment 124. Receptacle 144 is molded into the inside wall portion of boss 102 by sealing/forming mandrel 126 of blowing/filling nozzle 128. Continuous circumferential protuberance 125 having a wedge-shaped cross-section is machined into main mold parts 120 and 122 and forms groove 112, as well as the unitary frangible web 140 associated therewith, in cooperation with mandrel 126. The lowermost portion of mandrel 126 is provided with beveled edge 127 that molds shoulder 148. Thus, receptacle 144 in boss 102 of neck portion 98 is defined by inner wall portion 143 and continuous circumferential shoulder 148. Liquid pooling region 154 contiguous to shoulder 148 aids in gathering the liquid contents to be withdrawn from the container.

The downwardly sweeping motion of mandrel 126 as it forms shoulder 148 occasionally causes a berm of thermoplastic material to build up in the container neck portion near the juncture of the hollow boss 102 with the skirt portion 105 that connects to the container body portion, except at the mold parting line. Thus, even in the event of such a berm build-up, two opposed drain channels at the mold parting lines result and cause liquid to collect within the aforedescribed pooling region for withdrawal from the container.

Collar 129 on mandrel 126 is provided with annular sealing surface 131 that is situated at an angle of about 15 degrees to a plane normal to the longitudinal axis of mandrel 128. The upper bearing surface of circumferential protuberance 125 preferably is substantially parallel to annular sealing surface 130, thus the angle theta (θ) in FIGURE 4 preferably is also about 15 degrees.

For a typical unit dose container made of low density polyethylene and embodying the present invention the frangible web such as web 140 preferably has a thickness of about 0.005 inch to about 0.01 inch (about 0.13 mm to about 0.25 mm), and the thickness of the receptacle wall preferably is about 0.025 inch to about 0.03 inch (about 0.6 mm to about 0.8 mm) to provide elasticity and resilience.

The container is blow molded, with or without vacuum assist, after the sealing surface 131 is seated as shown in FIGURE 4, and thereafter filled with a liquid contents. The filled container is sealed, after blowing/filling nozzle 128 has been withdrawn, by conventional sealing molds (not shown) that come together above main mold parts 120 and 122 and crimp closed the upper end of parison segment 124. The contour of the opposed mold cavities in the sealing molds determines the shape of the upper portion of the unitary closure for the container.

The foregoing detailed description is intended to be illustrative of the present invention, and is not to be taken as limiting. Still other variants within the spirit and scope of this invention will readily present themselves to those skilled in the art.

Claims

1. A filled, hermetically sealed thermoplastic container having

   a hollow body portion closed at one end and terminating in an elongated neck portion at the other end thereof; and

   a closure unitary with said neck portion and joined to said neck portion by a peripheral

frangible web situated in a groove about the neck portion;

said neck portion having an inwardly extending, circumferential shoulder between said body portion and said frangible web, and defining with said shoulder a press-fit receptacle for a syringe tip between said frangible web and said shoulder.

2. The container in accordance with claim 1 wherein said receptacle has a length-to-width ratio of no more than about 1.

3. The container in accordance with claim 1 wherein said receptacle has a length-to-width ratio of about 0.6 to about 0.8.

4. The container in accordance with claim 1 wherein said neck portion is provided adjacent to said frangible web with an elastic hollow boss that defines said receptacle.

5. The container in accordance with claim 1 wherein said closure has the configuration of an ampoule tip.

6. The container in accordance with claim 1 wherein said closure has the configuration of a cap with a unitary grip tab extending therefrom.

Fig. 1 PRIOR ART

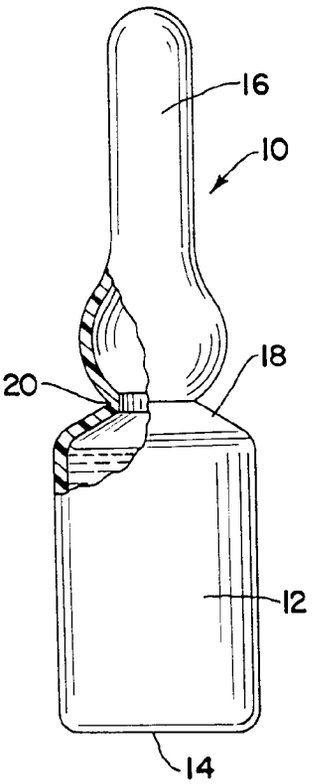


Fig. 2

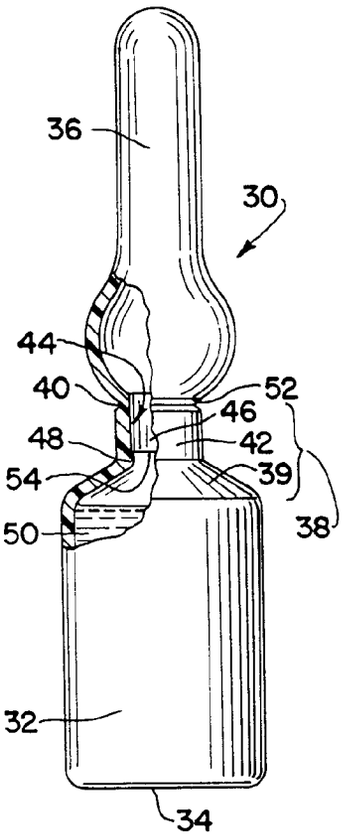


Fig. 3

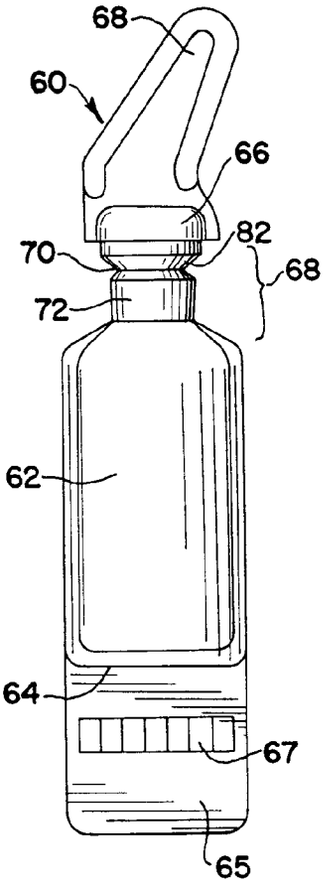
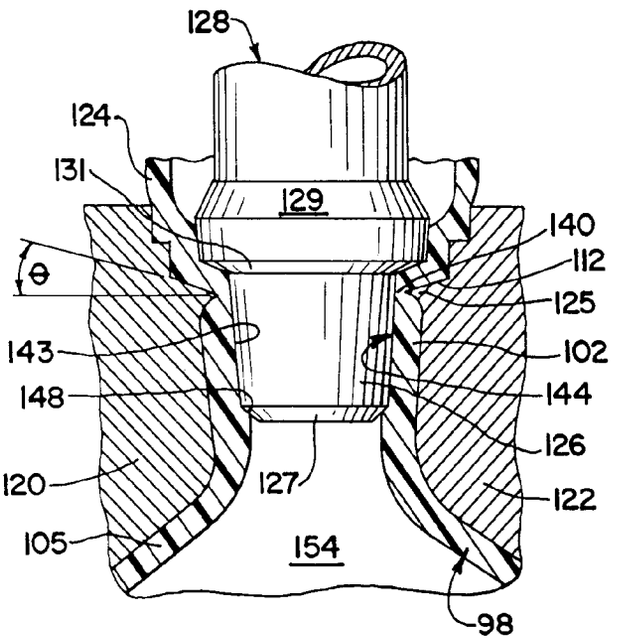


Fig. 4



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EUROPEAN SEARCH REPORT

Application Number

EP 91 31 1247

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 399 234 (HANSEN) * column 2, line 46 - column 3, line 24; figures 1-3 *	1,5,6	A61J1/06 B65D1/02
A	DE-A-2 152 589 (NAUMANN) * page 9, line 9 - line 20; figure 17 *	1	
A	US-A-3 993 223 (WELKER) * column 2, line 65 - column 3, line 12; figures *	1-3,5,6	
A,D	US-A-4 671 763 (WEILER) * column 5, line 6 - line 52; figures *	1-3,5,6	
A,D	US-A-4 643 309 (EVERS) * the whole document *	1,5,6	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61J
B65D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	03 MARCH 1992	BAERT F.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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