

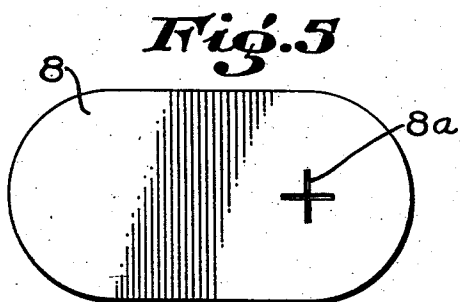
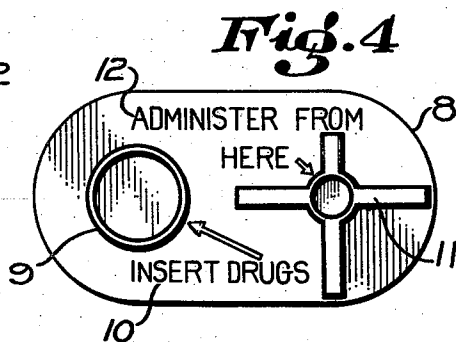
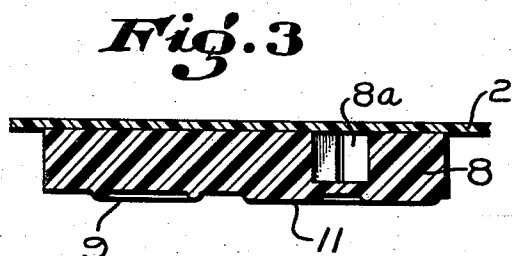
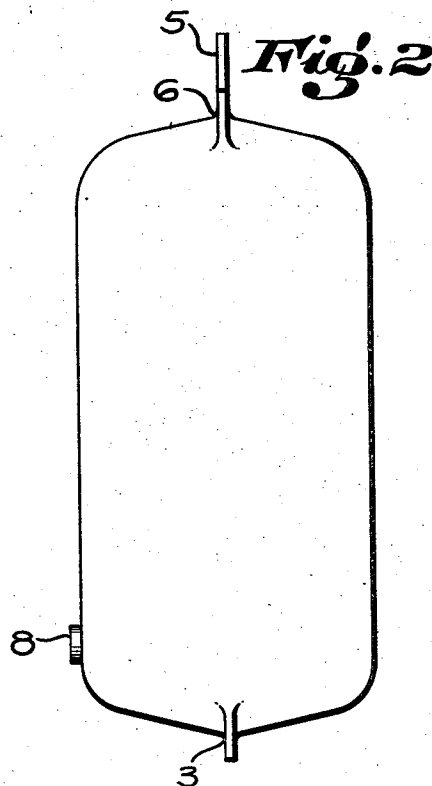
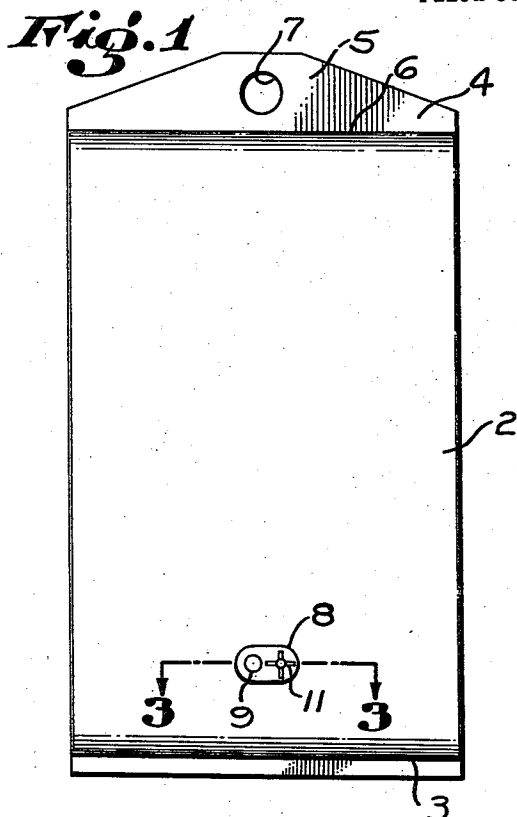
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PLASTIC CONTAINER

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PLASTIC CONTAINER

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13 Claims. (Cl. 128—272)

This invention relates to flexible plastic containers and refers particularly to such containers as are intended to hold a sterilized material, such as a pharmaceutical solution. The invention is concerned particularly with the provision of a leakproof, sterilizable entrance or entrances to the container for the injection of medication into the container or the removal of the contents of the container.

Problems arise in an attempt to market pharmaceutical solutions in flexible plastic containers. These flexible plastic containers are entirely sealed and therefore provide no entrance means. Attempts have been made to provide entry to the plastic container by use of a hypodermic needle inserted directly through the wall and by this means either add medication to the container or withdraw contents of the container. Difficulty arises from the fact that the walls of containers are so thin and flexible that the needle is easily dislodged from its position and there is a possibility of leakage of solution between the needle and the plastic wall. Moreover, if the needle is withdrawn leakage will result from the puncture through the container wall.

Proposals have been made to provide in the container a thickened portion through which the hypodermic needle is to be injected for the purpose of decreasing the tendency toward leakage but plastic materials have poor sealing properties. Rubber is a good self-sealing material but difficulties are encountered in finding a satisfactory method of attaching rubber entry pads to a plastic container.

It is a general object of the present invention to provide a plastic container with an improved entry pad which is easy and inexpensive to make and attach and which entry pad may allow entry to the container by a hypodermic needle without danger of the hypodermic needle being dislodged and without danger of leakage around the needle and from the opening formed by the needle after removal of the needle.

Another object of the present invention is to provide an entry pad which will not only permit entry and proper sealing with a hypodermic needle but which will also allow easy insertion of the larger pointed connector of an administration set.

We have found that an improved entry pad for a plastic container may be made from polyvinyl chloride (PVC) compounds which contain at least 60% of a suitable plasticizer, whereas with a normal amount of plasticizer (15–50%) polyvinyl chloride compounds have poor self-sealing properties. Furthermore, the highly plasticized entry pad may be attached to a flexible polyvinyl chloride container with any ordinary polyvinyl chloride cement.

Plastisols (liquid suspensions of resins in plasticizer) or extruded compounds may be used. Any usual or well-known plasticizer of polyvinyl chloride compounds may be used and include, for example, diisooctyl phthalate, di-(2-ethylhexyl) adipate, and methyl acetyl ricinoleate.

These entry pads are preferably designed to allow entrance in two manners and may be provided with suitable indicia of the proper position for making entrance

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both by a hypodermic needle and also by a connector of an administration set. On the rear side of the entry pad (the side facing the plastic container to which it is attached) there is a weakening of the pad either by cutting or molding a hole partially through the pad to facilitate entrance of the larger connector of an administration set.

The plastic container of the present invention, together with the entry pads therefor, will be more fully understood from the following description of the preferred form of the invention, which description is given in connection with the accompanying drawings, in which

Figure 1 is a plan view of the layflat tubing with an entry pad in position, the container being indicated in the collapsed position;

Figure 2 is a side elevation with the container expanded to hold a pharmaceutical solution;

Figure 3 is a fragmentary section on the line 3—3 of Figure 1;

Figure 4 is an enlarged plan view of the entry pad; and

Figure 5 is an enlarged rear view of the entry pad.

Referring to the drawings, the plastic container of the present invention is indicated as formed of a layflat tubing 2. By a layflat tubing, reference is made either to the production of an extruded tubing the walls of which are sufficiently flexible so that when unfilled the opposite sides of the extruded tubing may lay flat against each other, or to the production of tubing from flat sheets of plastic by folding the sheet around a mandrel and sealing the sheet into a tubing in which case again the plastic material used is sufficiently flexible so that the resulting tubing would, if empty, allow its sides to collapse and lay flat. Usually this layflat tubing is formed out of polyvinyl chloride plastic containing around 15 to 50% of plasticizer. It is within the purport of this invention that the containers formed of this layflat tubing may be simultaneously filled with the act of producing the containers so that as originally produced they would contain intravenous and other pharmaceutical solutions which would prevent their laying flat. Layflat containers may also be made by molding, blowing, dipping, etc.

Containers made out of sufficiently flexible plastic so that the same may lay flat when empty are desirable in the present invention since even if the containers are originally simultaneously filled and produced, it is desired that on the withdrawal of solution therefrom the container shall collapse after the solution is withdrawn. This action is an advantage over the present practice of marketing intravenous solutions in glass bottles. To withdraw the contents from glass bottles it is necessary to allow the entrance of air into the container. With the layflat type of container it is not necessary to allow entrance of air to withdraw the contents.

To form the container at one end along the area 3, the layflat sides of the tubing are sealed together, preferably by heat-sealing, and below the seal the produced container is severed from the remainder of the tubing, or from similar other containers also produced from the tubing. At the upper end of the produced container along the smooth area 4 the layflat sides are heat-sealed together to form the upper margin of the container, above which there is retained a triangular section 5 of the tubing, the walls of which are sealed together along the margin 6, which triangular section serves as a handle for the container and is provided with an opening 7 which provides means by which the container may be suspended in use.

During the process of producing the container it is possible to fill the container with a solution but if further medication is to be added before or during use of the solution it is necessary to provide some entry means. It

is also necessary to provide some means for removal of the contents. For this purpose near the lower end of the container there is provided the entry pad 8. This entry pad is made of polyvinyl chloride plastic compounds containing a suitable plasticizer. The plasticizer may be of the type usually used, such as diisooctyl phthalate, di-(2-ethylhexyl) adipate, and methyl acetyl ricinoleate. By the addition of the plasticizer the entry pad is made self-sealing, and moreover will seal to any hypodermic needle or administration set connector inserted through the entry pad. To adequately secure these properties we have found it is desirable to have from 60% to 90% of plasticizer present. We have found it preferable in the practice of the present invention to use layflat tubing in making the containers of the present invention which have about 35% plasticizer although they may contain from 15% to 50% plasticizer and it may be found beneficial to use entry pads containing about 70% plasticizer although the entry pads may contain from 60% to 90% plasticizer.

An entry pad of sufficient thickness to have proper sealing properties with a hypodermic needle in place, and also sufficiently thick to be self-sealing after the hypodermic needle is withdrawn, is provided when the entry pad is in the neighborhood of $\frac{5}{32}$ inch in thickness. Addition thus may be made to a plastic container having an entry pad of the present invention by hypodermic needle, and also the contents of the container may be withdrawn by hypodermic needle attached to a suitable withdrawal tubing.

It is desirable to withdraw the contents of the container by the use of administration set connectors which are considerably larger in diameter than the points of hypodermic needles. The standard larger administration sets could thus be used and moreover a firmer connection made with the container. Since the containers of the present invention, particularly when filled with solution, are not rigid, it is not practicable to seek entrance to such containers by using spikes or puncture points of considerably larger diameter than hypodermic needles through an entrance area of substantial thickness. It is, therefore, important to the production of a satisfactory plastic container of the type of the present invention that there be means to permit entrance of spikes or puncture points without encountering a large resistance. This entrance cannot be effected satisfactorily by merely undercutting the entrance pad with a round or ordinary type opening at the puncture area. If a small hole is cut partially through the entry pad from the rear face at the location where the spike or puncture point is to be inserted, difficulty is still experienced in inserting the puncture point. If there is a large hole in the rear face of the entry pad the entry pad tends to blow off the container during heat sterilization.

We overcome this in the present invention by providing a cross-like opening 8a from the rear side in place of a round opening. This cross-like opening extends preferably about 80% through the entry pad and the cross-like opening may be formed merely by cutting or scoring so that actually the cut walls of the cross-like openings are closed or in contact, leaving substantially no air space, or in other cases the cross-like opening may be molded, in which case the separation of the sides of the cross-like opening should be kept rather narrow, such as round $\frac{1}{100}$ of an inch. In this way there is formed only a very small airpocket at the rear of the pad, yet the cross-like opening cut or molded in the rear of the pad readily allows an expansion on the insertion of the connector, while at the same time preserving tight sealing properties of the entry pad.

The entry pad of the present invention may also be provided on its front face with suitable indicia for indicating the areas for entrance to the container by a hypodermic needle and for indicating the suitable place for making entrance to the container when the larger diam-

eter instrument, such as an administration set connector, is to be used. Thus in the present example indicia are molded into the entry pad and as illustrated there is a molded circular indicia 9 with the legend 10 which marks a suitable unweakened portion of the entry pad for the insertion of hypodermic needles. There is also a cross-like indicia 11 with the legend 12 for marking the weakened area of the entry pad where the operator should make entry when using the larger diameter device.

The entry pads of the present invention are easily attached to the containers by any ordinary polyvinyl chloride cement. For example, cements may be provided by dissolving polyvinyl chloride compound in a solvent such as tetrahydrofuran or cyclohexanone. These entry pads are found to have good sealing properties and yet permit the ready and rapid withdrawal of the contents of the container.

Entry pads of the present invention may be useful in other applications. They may, for example, be attached to the drip chamber of plastic tubes of an administration set where they can serve as a site for injection of drugs or other medication.

While the particular form of the invention herein described is well adapted to carry out the objects of the present invention, this invention is of the scope set forth in the appended claims.

We claim:

1. A layflat plastic container, the body of which is formed of layflat polyvinyl chloride tubing having fifteen to fifty percent plasticizer, the layflat sides of said tubing being sealed together at opposite ends to form a container, the container being provided with an entry pad which furnishes a resilient thickened section for self-sealing and holding a needle piercing the same, said pad being attached to the tubing, said pad being formed of polyvinyl chloride, the entry pad containing from 60% to 90% plasticizer.

2. A layflat plastic container, the body of which is formed of layflat polyvinyl chloride tubing, the layflat sides of said tubing being sealed together at opposite ends to form a container, the container being provided with an entry pad which furnishes a resilient thickened section for self-sealing and holding a needle piercing the same, said pad being attached to the tubing, said pad being formed of polyvinyl chloride and containing a plasticizer, the entry pad having a partial cross-like opening.

3. A layflat plastic container, the container being formed of an extruded layflat polyvinyl chloride tubing, the layflat sides of which are sealed together at spaced-apart points to form the container, the container being provided with an entry pad forming a resilient thickened section for self-sealing and holding a needle piercing the same, said entry pad being cemented to the tubing and being formed of a polyvinyl chloride having a plasticizer, the entry pad having indicia at suitable areas for entrance by both hypodermic needles and larger diameter entrance means, the entry pad having a partial opening of limited volume between said latter indicia area and said tubing.

4. A layflat plastic container, the container being formed of an extruded layflat polyvinyl chloride tubing, the layflat sides of which are sealed together at spaced-apart points to form the container, the container being provided with an entry pad forming a resilient thickened section for self-sealing and holding a needle piercing the same, said entry pad being attached to the tubing and being formed of a polyvinyl chloride having a plasticizer, the entry pad having indicia of suitable areas for entrance by both hypodermic needles and larger diameter entrance means, the entry pad having a partial opening on its rear surface at said latter indicia area, the partial opening being in the form of a cross.

5. A layflat plastic container, the body of which is formed of layflat plastic, the container being provided with a thickened entry pad which furnishes a resilient

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thickened section for self-sealing and holding a needle piercing the same, the entry pad having a cross-like opening extending but partially through the pad from the rear face thereof.

6. An entry pad for a plastic container, said entry pad being formed of polyvinyl chloride and containing from 60% to 90% plasticizer, the entry pad having a partial cross-like opening.

7. An entry pad for a plastic container, said entry pad being formed of polyvinyl chloride and containing from 60% to 90% plasticizer, the entry pad having a partial cross-like opening, the entry pad having indicia on the side opposite the location of said partial opening.

8. A layflat plastic container, the body of which is formed of layflat polyvinyl chloride plastic, the container being provided with a thickened entry pad which furnishes a resilient thickened section for self-sealing and holding a needle piercing the same, the entry pad being attached to the container by an adhesive, said pad being formed of polyvinyl chloride containing from 60% to 90% plasticizer.

9. A layflat plastic container comprising: a collapsible body formed of polyvinyl chloride containing fifteen to fifty percent plasticizer and suitable for storage of injectable solutions; a separate entry pad cemented to said body to provide a resilient thickened section for self-sealing and holding a needle piercing the same, said pad being formed of polyvinyl chloride and containing from sixty to ninety percent plasticizer.

10. A layflat plastic container, the body of which is formed of layflat plastic, the container being provided

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with a thickened entry pad which furnishes a resilient thickened section for self-sealing and holding a needle piercing the same, the entry pad having a slit-like opening extending partially through the pad from the rear face thereof.

11. A plastic container according to claim 9, in which the entry pad has a slit-like opening extending partially through the pad from the rear face thereof.

12. A plastic container according to claim 9, in which the entry pad has an opening of limited volume extending partially through the pad from the rear face thereof.

13. A layflat plastic container, the body of which is formed of layflat plastic, the container being provided with a thickened entry pad which furnishes a resilient thickened section for self-sealing and holding the needle piercing the same, the entry pad having an opening of limited volume extending partially through the pad from the rear face thereof.

References Cited in the file of this patent

UNITED STATES PATENTS

2,301,128	Landefeld	Nov. 3, 1942
2,442,983	Neset	June 8, 1948
2,457,120	Brandon	Dec. 28, 1948
2,642,866	Smith	June 23, 1953
2,704,075	Cherkin	Mar. 15, 1955

OTHER REFERENCES

Organic Chemistry, Fieser and Fieser, copyright 1944, pp. 344, 346, 915.