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(54) INSERTS FOR MULTIPLE COMPONENT **CONTAINERS**

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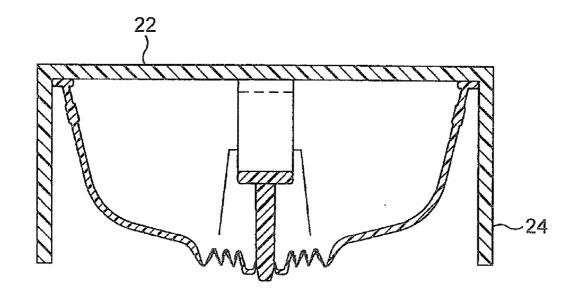
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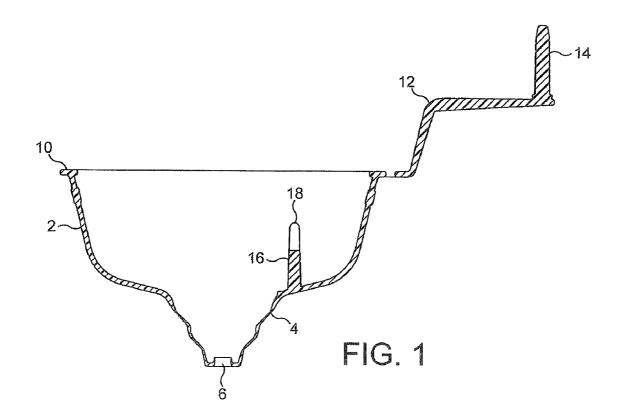
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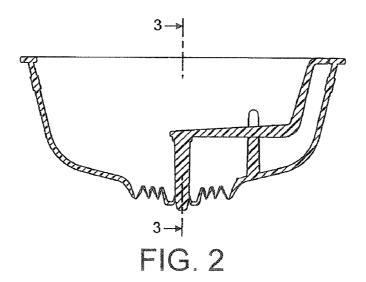
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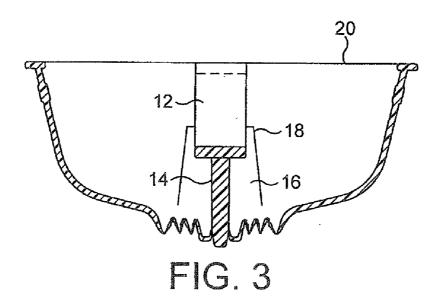
ABSTRACT (57)

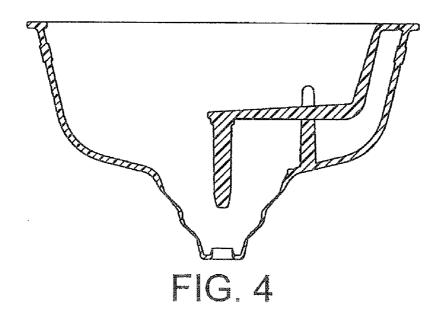
An insert for a multiple component container includes a diaphragm and a sealing element which together define a reservoir. The diaphragm includes a stationary portion and a movable portion. The movable portion is connected to the stationary portion by at least two spaced annular fold lines of opposite sense. A discharge opening is formed in the movable portion within the annular fold lines. A gas leakage path is provided in the diaphragm. A valve member is connected to the stationary portion and cooperates with the discharge opening and substantially seals it. If a great gas pressure is applied to the interior of the reservoir than to its exterior, this results in rotational movement about the fold lines and thus in movement of the movable portion away from the stationary portion and thus in the valve member moving out of sealing contact with the flow opening. Any liquid in the reservoir is then expelled through the discharge opening by the higher pressure prevailing within the reservoir.

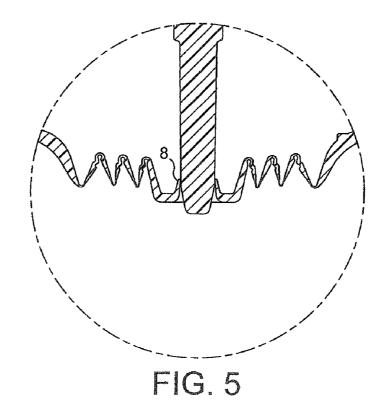


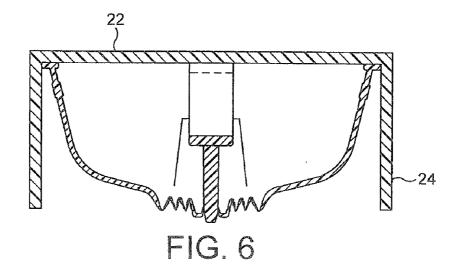












INSERTS FOR MULTIPLE COMPONENT CONTAINERS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to British Application No. GB 0601018.5 filed on Jan. 18, 2006, the entire disclosure of which is hereby incorporated by reference.

Field of the Invention

[0002] The present invention relates to inserts for multiple component containers, which contain two or more different substances or components which are stored separately but are mixed together at the time the container is opened.

Description fo the Prior Art

[0003] There are many fields in which multiple component, particularly binary component, containers are used or are desirable. Thus, there are certain pharmaceutical compositions which are administered in the form of a mixture but which are unstable in the long term in the form of a mixture. The components of such a composition are therefore stored separately and only mixed shortly before administration. In this case, both components are generally in liquid form but it is also possible for one of the components to be in solid or powder form. Such containers may also find application in the foodstuff market, particularly for beverages. Thus it is desirable, for instance in connection with canned or bottled lager and lime, only to mix the lime into the lager shortly before consumption of the beverage.

[0004] It is the object of the invention to provide an insert for a multiple component container which is simple and cheap and which enables one component in the container to be reliably automatically mixed with a second component in the container as the container is opened.

SUMMARY OF THE INVENTION

[0005] According to the present invention, an insert for a multiple component container includes a diaphragm and a sealing element which together define a reservoir, the diaphragm including a stationary portion and a movable portion, the movable portion being connected to the stationary portion by at least two spaced annular fold lines of opposite sense, a discharge opening being formed in the movable portion within the annular fold lines, a gas leakage path being provided in the diaphragm, a valve member connected to the stationary portion and cooperating with the discharge opening and substantially sealing it, whereby the application of a greater gas pressure to the interior of the reservoir than to its exterior results in rotational movement about the fold lines and thus in movement of the movable portion relative to the stationary portion and thus in the valve member moving out of sealing contact with the flow opening.

[0006] In use, the insert will be partially filled with one component, preferably in liquid form, of a multiple component system and will be placed inside a container including a further component of the multiple component system. Once the container has been sealed by means of a lid or other closure, which may be separate from the insert or may be connected to it, the interior of the container, that is to say the head space above the component situated within it, is pressurised. If the component with the container is a car-

bonated beverage, this pressurisation will occur automatically by virtue of the progressive release of carbon dioxide from it. If, however, the component within the container is not carbonated and is e.g. a pharmaceutical preparation, this pressurisation of the head space of the container may be conveniently effected by adding a few drops of e.g. liquid nitrogen into the container immediately before it is sealed. Vaporisation of the nitrogen will commence immediately and the initial vaporisation will result in the atmospheric air in the head space being replaced by the nitrogen. Subsequent vaporisation of the nitrogen after application of the sealing lid will result in pressurisation of the head space. The gas leakage path in the diaphragm will progressively admit pressurised gas into the interior of the reservoir, whereby the pressure within the reservoir will reach a value substantially the same as that in the pressurised head space of the container. When the container lid is removed, the head space of the container will be instantly depressurised. However, the leakage path in the diaphragm is sufficiently small that instant depressurisation of the interior of the reservoir is not possible, whereby a substantial pressure differential across the diaphragm will be created. This will act on the movable portion of the diaphragm and will result in relative rotation of the annular portions of the diaphragm on each side of each fold line. This relative rotation will result in movement of the movable portion away from the stationary portion and thus in movement of the discharge opening away from the valve member. This movement is sufficient to move the discharge opening out of cooperation with the valve member, whereby the discharge opening is now open. The gas pressure prevailing within the reservoir will then expel the component within the reservoir through the discharge opening and into the body of the container, where it will mix with the other components present therein. The container now contains a two-component mixture which may then be administered to a patient or otherwise used.

[0007] The valve member may take various forms but in a simple preferred embodiment, it constitutes a spigot or the like which is integrally connected to the diaphragm. This spigot will normally cooperate with the discharge opening, e.g. extend into it and form a seal with it, so as to close the discharge opening and prevent premature discharge of the component within the reservoir into the container. It is convenient for manufacturing reasons for the valve member to be integral with the peripheral edge of the diaphragm and this will necessitate the spigot being connected to the edge of the diaphragm by means of a link or connector of some sort. This link will inherently be relatively long and in order to ensure that it is retained in the desired position, it is preferred that the insert includes a support member integral with the stationary portion which is engaged by the link and stabilises it.

[0008] The gas leakage path in the diaphragm may be constituted simply by a very small hole in it. It is, however, convenient if the valve member and discharge opening together define the gas leakage path because this will obviate the necessity of forming a separate leakage path. It is preferred that the valve member and discharge opening together constitute a one-way valve defining the gas leakage path through which gas may flow into the reservoir but not out of it.

[0009] The insert may be used with two-component containers and in this event one component will of course be

stored in the body of the container and the other in the insert. The invention is, however, applicable to containers for three or more component systems and thus the reservoir may include one or more partitions dividing it into two or more compartments, each of which communicates with a respective flow opening cooperating with a respective valve member. In use, each compartment will of course be filled with a different component of the multi-component system. In this event, it is preferred that each flow opening is associated with a respective set of at least two spaced annular fold lines.

[0010] The insert will of course need to be sealed prior to use to prevent leakage or contamination of its contents and the sealing element may be a sheet of plastic material or of metal or a composite thereof sealingly connected to the peripheral edge of the diaphragm.

[0011] The insert may be applied to a container in the form of a discrete component and the lid or other closure subsequently applied to the container. It is, however, convenient if the insert and closure constitute a composite unit, whereby they are then applied simultaneously to the container. Such a closure will include a closure plate which, in use, extends across a dispensing opening in the container and it is therefore possible for the sealing sheet of plastic material or the like to be omitted and for the closure plate of the closure to constitute the sealing element of the insert.

[0012] Further features and details of the invention will be apparent from the following description of certain specific embodiments which is given by way of example only with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is an axial sectional view of a first embodiment of an insert in accordance with the present invention in the "as-moulded" state;

[0014] FIG. 2 is an axial sectional view of the insert of FIG. 1 in the operative configuration;

[0015] FIG. 3 is an axial sectional view on the line 3-3 in FIG. 2:

[0016] FIG. 4 is a view similar to FIGS. 1 and 2 showing the insert after its contents have been expelled into a container:

[0017] FIG. 5 is a scrap view on an enlarged scale showing the valve spigot located in the flow opening; and

[0018] FIG. 6 is a view similar to FIG. 3 showing a container cap incorporating an insert in accordance with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0019] The insert illustrated in the accompanying drawings constitutes a one-piece moulding of polypropylene or the like. It could, however, also be made from metallic foil or from a composite comprising metal and plastics material which is stamped or pressed into shape. When the insert is ejected from the mould, it has the configuration shown in FIG. 1. It comprises an open-topped, generally cup-shaped member 2, formed in whose base is a depending pocket 4. The downwardly and inwardly inclined annular wall of the pocket 4 is formed with a plurality of spaced, annular lines

of weakness, that is to say lines of reduced thickness, whose function will be described below. Formed in the base of the pocket 4 is a flow opening 6, which is defined by a flexible marginal lip 8, seen in FIG. 5. Moulded integrally with the upper peripheral edge 10 of the insert constitutes a peripheral flange 10, moulded integrally with which is one end of an elongate connector link 12, which extends generally laterally. Integral with the free end of the link 12 is a spigot 14, which extends vertically upwardly in the as-moulded state. Moulded integrally with the base of the cup-shaped member 2, radially outside the pocket 4, is an upstanding support 16. The support 16 comprises an upstanding web, at the two ends of whose upper surface there are respective upstanding lugs 18, the space between which is substantially equal to the width of the link 12. The support 16 thus affords a generally rectangular recess at its upper end defined by the inner edges of the two lugs 18.

[0020] The insert is now brought into the operative configuration by applying an upward force to the lower end of the pocket 6. This results in the annular wall of the pocket 4 corrugating, that is to say folding about the annular lines of weakness, adjacent folds being of opposite sense. The pocket 4 is moved upwardly until it is generally at the same level as the remainder of the base of the cup-shaped portion 2. Prior or subsequent to this, the link 12 is rotated through 180□ in the anticlockwise direction, as seen in FIG. 1, until it reaches the position shown in FIG. 2. The free end, which is of frustoconical shape in this case, of the spigot is inserted into the opening 6 defined by the upwardly extending lip 8. The internal diameter of the lip 8 and the external diameter of the spigot 14 are so matched to one another that the spigot 14 expands the lip 8 outwardly, whereby the lip 8 is urged into contact with the surface of the spigot 14 and thus forms a substantial gas seal with it. When in this position, the link 12 is supported on the upper surface of the support 16 and restrained from lateral movement by the lugs 18.

[0021] The insert is then partially filled with the desired substance, in liquid or powder form, and in the present case it will be assumed that this substance is one component of a two-component pharmaceutical composition which is administered in the form of a mixture but is unstable in the long term in the form of a mixture. The insert is then sealed by connecting to the upper surface of its upper peripheral flange 10 a sealing film 20, preferably of metalized plastic material because such composite materials are impermeable to both liquids and vapours. The insert is now ready for use.

[0022] The insert may be used in a variety of ways but in its simplest form it is placed within the neck of a binary component container, which already contains the other component of the two-component pharmaceutical composition referred to above, with its peripheral flange 10 resting on the rim of the container. Before positioning the insert on the rim of the container, a few drops of liquid nitrogen are inserted into the container and an outer sealing lid is then rapidly applied before all the nitrogen has vaporised. The initial vaporisation of the liquid nitrogen will fill the head space of the container with nitrogen and displace all atmospheric air and any bacteria contained therein. The subsequent vaporisation of the nitrogen, which occurs after application of the lid, will increase the pressure in the head space of the container to a super-atmospheric level. As this pressure increases, the lip 8 will yield outwardly to open up a small gas leakage path into the interior of the insert. The pressure

in the interior of the insert will therefore over time reach a value substantially equal to that in the head space of the container.

[0023] When it is desired to administer the two-component pharmaceutical composition, the container lid is removed. This will result in instant depressurisation of the head space of the container. However, the valve constituted by the engagement of the lip 8 with the spigot 14 is a one-way valve, by virtue of the orientation of the lip 8. The interior of the insert is thus not instantly depressurised and there is therefore a substantial pressure differential across the wall of the pocket 4. This results in instantaneous movement of the pocket downwardly accompanied by simultaneous unfolding of the various folds in its annular wall, this unfolding being in opposite senses in adjacent folds. As the lower portion of the pocket moves downwardly, the rim 8 of the flow opening 6 will move out of contact with the spigot 14, which is stationary. The flow opening 6 is now unobstructed and the super-atmospheric pressure prevailing in the interior of the insert above the pharmaceutical component within it now acts to expel the pharmaceutical component rapidly through the opening 6 into the container, where it will mix with the pharmaceutical component already in the container with the aid of the mixing action produced by the high speed jet through the opening 6. The pocket may be so dimensioned and the container may be filled to such a level that the opening 6 is situated below the level of the liquid in the container, though this is not essential. The insert will now be in the configuration shown in FIG. 4 and may be discarded. The twocomponent pharmaceutical composition may now be administered to the patient.

[0024] As described above, the insert in accordance with the invention and the closure or lid are applied to the container separately. It may, however, be more convenient to integrate the insert with the lid and such a construction is shown in FIG. 6. Such an integrated construction may comprise an insert as illustrated in FIGS. 1 to 5 secured within the lid, e.g. by virtue of a push-fit or by adhesive or the like. However, this lid will necessarily have a cover plate, designated 22 in FIG. 6, which will extend over the opening in the container and possibly also a depending peripheral skirt 24, bearing a screw thread or the like (not shown) if the container is of conventional type with a dispensing opening formed in a neck. The presence of the closure plate 22 opens up the possibility of omitting the sealing film 20, the function of which is then fulfilled by the cover plate 22, which is sealed by any appropriate means to the upper flange 10 of the insert.

[0025] It will be appreciated that the insert and lid described above are for use with a binary component container, that is to say a container which contains one component in the body of the container and a second component to be mixed with it in the insert. However, the insert and lid in accordance with the invention can also be used for containers to contain three or more different components to be mixed shortly before use or administration. Thus in a modified embodiment, which is not illustrated, the insert is for use with a container to contain three different components. The base of the cup-shaped member 2 is formed with two sets of annular, preferably concentric, fold lines of opposite sets, a respective discharge opening being situated within each set of fold lines. The interior of the reservoir

defined by the insert is divided into two compartments by a partition which is integral with the wall and base of the insert and extends between the two sets of fold lines, whereby each of the compartments communicates with a respective flow opening. Also integrally formed with the cup-shaped member are two spigots and links, substantially the same as that illustrated in the figures, cooperating with respective flow openings. It will be appreciate that, in use, the two compartments will be filled with different components and that operation of the insert is essentially the same as that described above, the only difference being that when the container is opened both flow openings will move downwardly and thus move out of contact with the associated spigots, whereby the two flow openings will be opened substantially simultaneously and the contents of the two compartments will be expelled into the body of the container substantially simultaneously and will be mixed with the third component already present in the body of the container.

What is claimed is:

- 1. An insert for a multiple component container, said insert including a diaphragm to define a reservoir having an open top, said diaphragm including a stationary portion and a movable portion, said movable portion being connected to said stationary portion by at least two spaced annular fold lines of opposite sense, a discharge opening being formed in said movable portion within said annular fold lines, a gas leakage path being provided in said diaphragm, a valve member connected to said stationary portion and cooperating with said discharge opening and substantially sealing it, whereby the application of a greater gas pressure to the interior of said reservoir than to its exterior results in rotational movement about the fold lines and thus in movement of said movable portion relative to said stationary portion and thus in said valve member moving out of sealing contact with said flow opening.
- 2. An insert as claimed in claim 1 further comprising: a sealing element across said open top of said diaphragm.
- 3. An insert as claimed in claim 1 wherein said diaphragm has a peripheral edge and said valve member constitutes a spigot which is integrally connected to said peripheral edge of said diaphragm.
- **4**. An insert as claimed in claim 3 which includes a support member integral with said stationary portion and said spigot is connected to said peripheral edge of said diaphragm by a link which engages and is stabilised by said support member.
- 5. An insert as claimed in claim 1 in which said valve member and said discharge opening together define said gas leakage path.
- **6**. An insert as claimed in claim 5 in which said valve member and said discharge opening together constitute a one-way valve defining said gas leakage path through which gas may flow into said reservoir but not out of it.
- 7. An insert as claimed in claim 1 including at least two valve members in which at least two discharge openings are formed in said movable portion which cooperate with a respective one of said valve members and said reservoir includes at least one partition dividing it into at least two compartments and each of said compartments communicates with a respective discharge opening.
- **8**. An insert as claimed in claim 7 in which each of said discharge openings are associated with a respective set of at least two spaced annular fold lines.

- **9**. An insert as claimed in claim 2 in which said sealing element is a sheet of plastic material or metal or a composite thereof sealingly connected to said peripheral edge of said diaphragm.
- 10. An insert as claimed in claim 2 wherein said sealing element is a closure plate adapted to close the opening in the container with which the insert is to be used.
- 11. An insert for use in a multiple component container comprising:
 - a generally cup shaped body having an open top, an upper wall portion and a lower wall portion,
 - said lower wall portion including a distensible wall portion,
 - said distensible wall portion having a normal non-distended first state and a distended second state,
 - said distended second state occurring in response to a differential pressure across the wall of said insert,
 - a valve opening in said distensible wall portion,
 - a valve member mounted to said insert for engagement with said valve opening when said distensible wall portion is in said first state,
 - said valve member and said valve opening disengaging in response to distension of said distensible wall portion.
 - 12. The insert of claim 11 further comprising:
 - a sealing membrane across said top of said cup shaped body.
 - 13. The insert of claim 11 further comprising:
 - a container lid across said top of said cup shaped body to seal the top of said body, said lid being adapted to be applied to the top of the container to close the container.
 - 14. The insert of claim 11 further comprising:
 - a resilient sealing lip at said valve opening, said lip being responsive to differential pressure across said distensible wall portion to provide a leakage path into said insert to equalize pressure within said insert to whatever pressure is in the container with which said insert is used.
 - 15. The insert of claim 12 further comprising:
 - a resilient sealing lip at said valve opening, said lip being responsive to differential pressure across said distensible wall portion to provide a leakage path into said

- insert to equalize pressure within said insert to whatever pressure is in the container with which said insert is used.
- 16. The insert of claim 13 further comprising:
- a resilient sealing lip at said valve opening, said lip being responsive to differential pressure across said distensible wall portion to provide a leakage path into said insert to equalize pressure within said insert to whatever pressure is in the container with which said insert is used.
- 17. An insert for use in a multiple component container comprising:
 - a generally cup shaped wall,
 - said wall including a distensible wall portion,
 - said distensible wall portion having a normal non-distended first state and a distended second state,
 - said distended second state occurring in response to a differential pressure across said wall of said insert,
 - a valve opening in said distensible wall portion,
 - a valve member mounted to said insert for engagement with said valve opening when said distensible wall portion is in said first state,
 - said valve member and said valve opening disengaging in response to distension of said distensible wall portion.
 - **18**. The insert of claim 17 further comprising:
 - an opening across a top of said cup shaped wall, and a sealing membrane across said opening of said cup shaped wall.
 - 19. The insert of claim 17 further comprising:
 - an opening across a top of said bowl shaped wall,
 - a container lid across said top of said cup shaped wall to seal said top of said cup, said lid being adapted to be applied to the top of the container with which said insert is to be used to close the container.
 - 20. The insert of claim 18 further comprising:
 - an opening across a top of said bowl shaped wall,
 - a container lid across said top of said cup shaped wall to seal said top of said cup, said lid being adapted to be applied to the top of the container with which said insert is to be used to close the container.

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