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(54) **METHOD AND ARTICLE FOR PACKAGING DOSED PRODUCTS**

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(57) **ABSTRACT**

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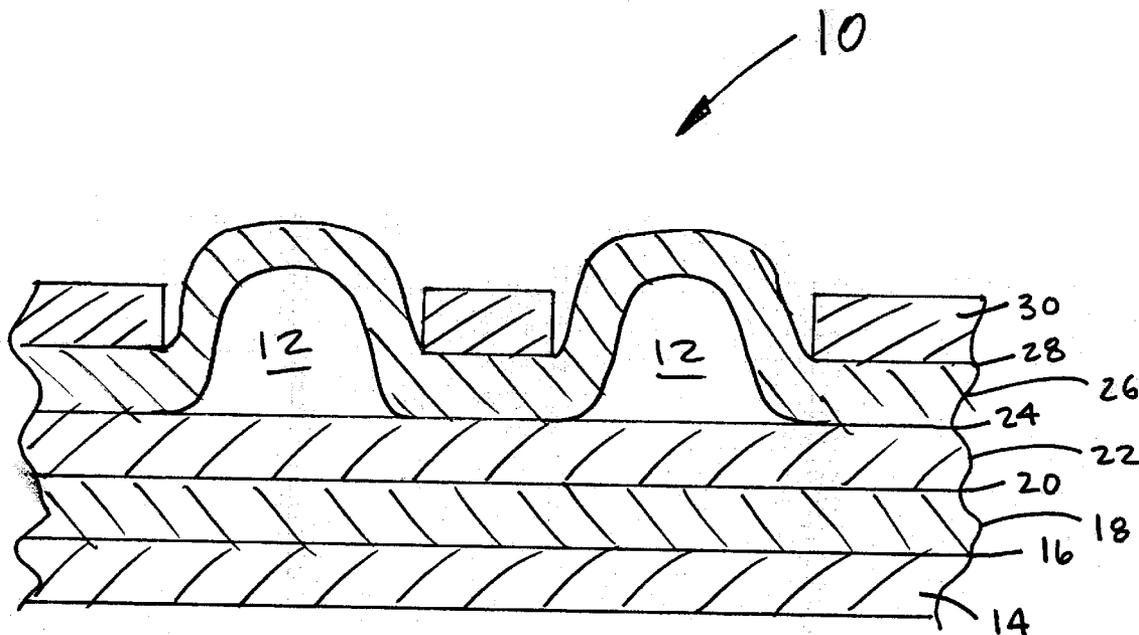
The present invention provides a child-resistant package for a dosed-form product having a blister layer, a rupturable layer disposed adjacent the blister layer, the rupturable layer and the blister layer together defining at least one cavity, a diaphragm layer for resisting passage of a dose, the diaphragm layer disposed adjacent the rupturable layer on a side of the rupturable layer opposite the blister layer, and a backing layer having at least one moveable tab corresponding to the at least one cavity, the backing layer disposed adjacent the diaphragm layer on a side of the diaphragm layer opposite the rupturable layer. Also included are methods of packaging dosed products in accordance with the invention.

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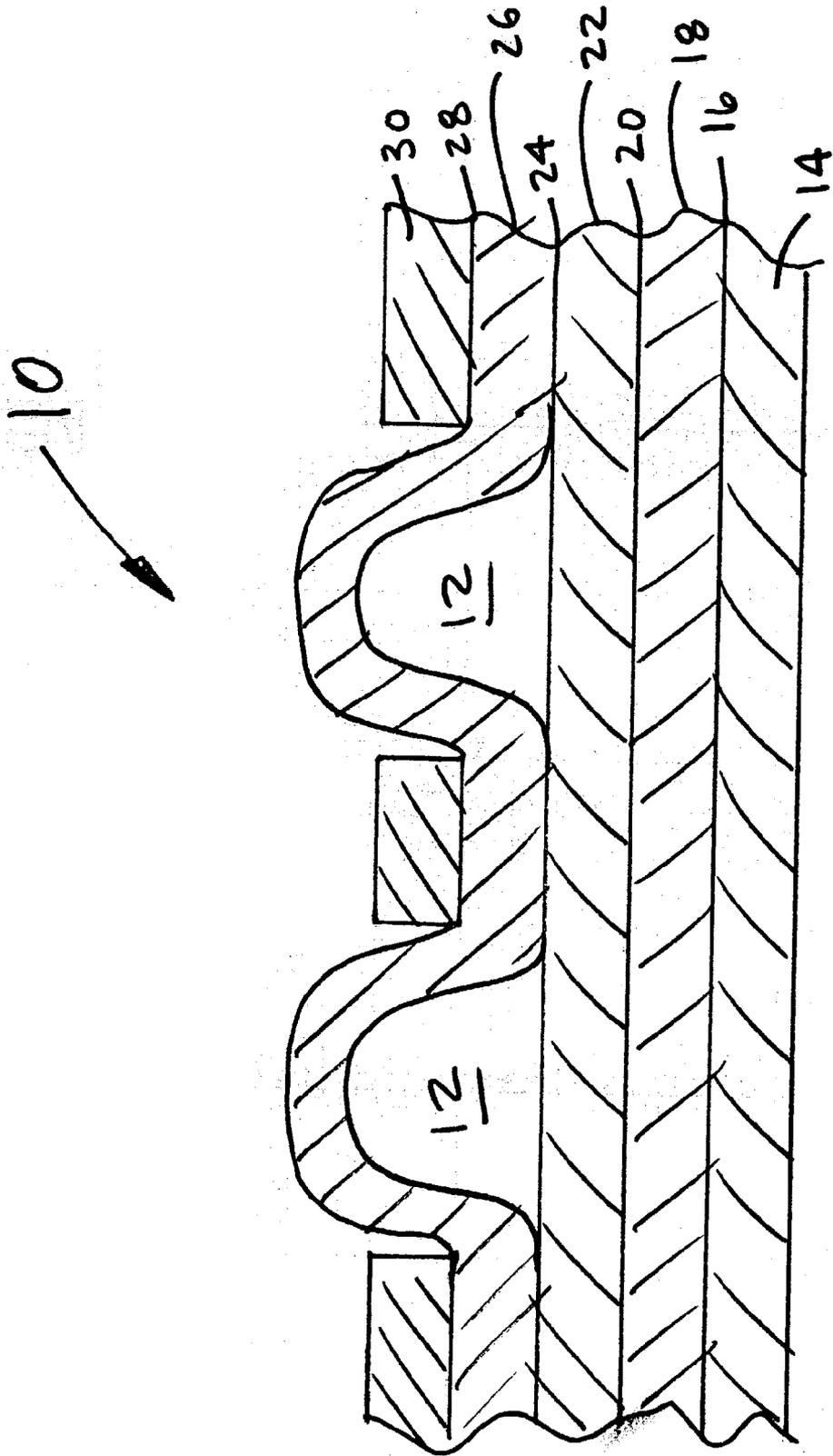


FIG. 1

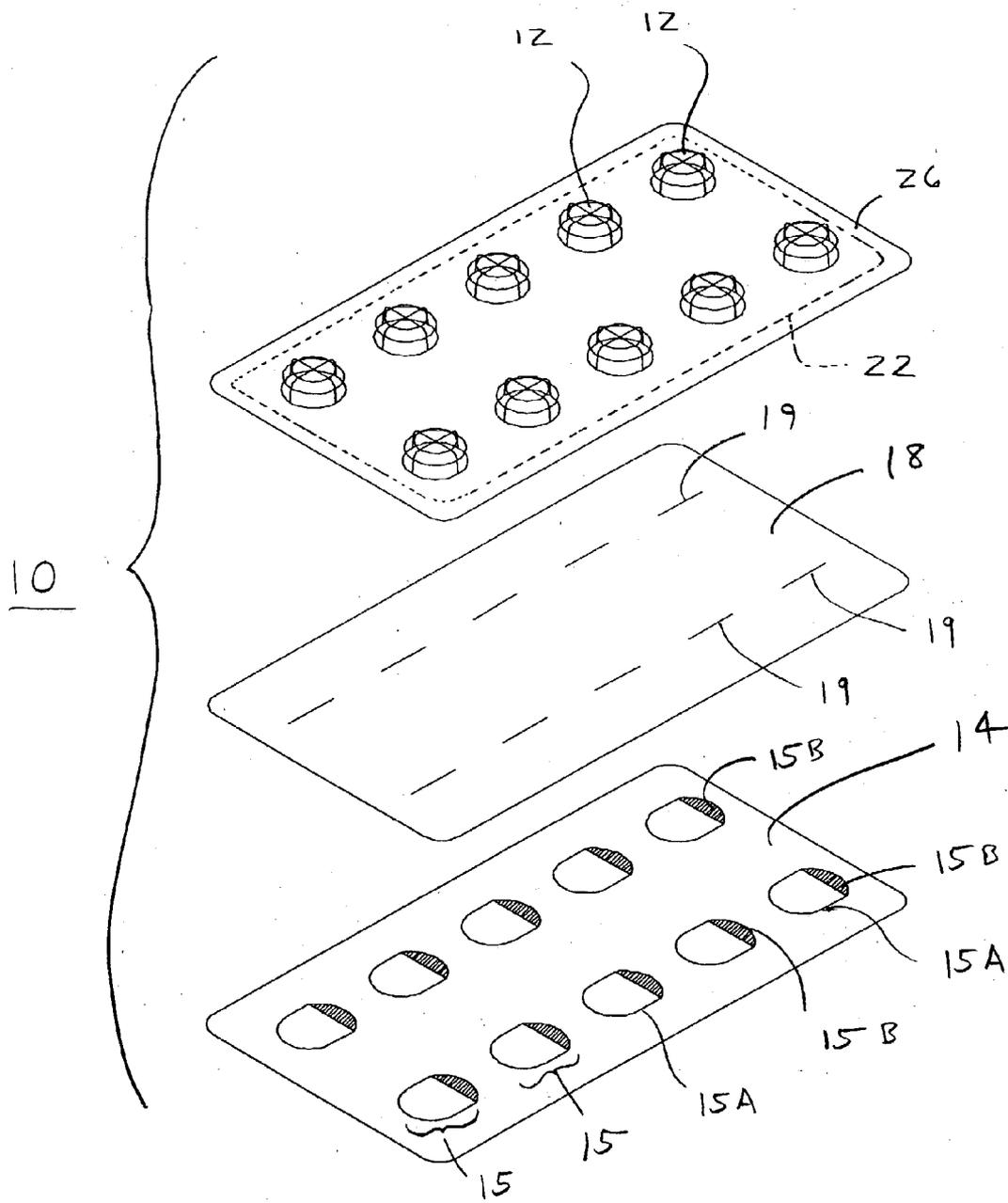


FIG. 2

METHOD AND ARTICLE FOR PACKAGING DOSED PRODUCTS

BACKGROUND OF THE INVENTION

[0001] It is known to use blister packages to contain small articles such as pharmaceutical or dose form products. These packages allow the user to access the product by applying pressure to the blister to force the product from an individual blister or capsule through a rupturable layer.

[0002] Known blister packages comprise a first sheet of transparent or translucent thermoformable material such as polyvinyl chloride or polystyrene having a plurality of flexible blisters or blisters preformed therein and projecting outwardly from one surface to define separate compartments for individual doses of a product, typically a single tablet or capsule, and a second sheet to cover the product. The second sheet is often made from a rupturable foil or a paper-foil combination so that the user can push the product from the blister side out through the foil. This construction did not offer much in the way of child resistance, and presented a potential hazard to children.

[0003] In order to render blister packages resistant to access by children, improved child-resistant blister packages have been developed. Exemplary structures of such child-resistant blister packages, as well as exemplary methods of forming such packages, are disclosed in U.S. Pat. No. 6,161,699 to Gartland, which is hereby incorporated by reference herein.

[0004] Despite the fact that such child-resistant packages have improved safety characteristics, there is room for further improvements. Many of the known package-forming methods and package constructions, although offering varying degrees of child resistance, sometimes compromised accessibility. Specifically, in some cases, known methods and constructions made the product so inaccessible that even adults had trouble accessing the product. This later case is especially problematic where older adults or others who have lost some degree of manual dexterity are the users of the products.

[0005] Thus, there remains a need for an improved packaging method and construction that provide the desired level of resistance to a child while maintaining acceptable levels of accessibility for adults.

SUMMARY OF THE INVENTION

[0006] The present invention provides a child-resistant package for a dosed-form product comprising a film blister layer, a rupturable layer disposed adjacent the film blister layer, the rupturable layer and the film blister layer together defining at least one cavity, means for resisting passage of a dose, the means disposed adjacent the rupturable layer on a side of the rupturable layer opposite the film blister layer, and a backing layer having at least one moveable tab corresponding to the at least one cavity, the backing layer disposed adjacent the means for resisting on a side of the means opposite the rupturable layer.

[0007] An alternative embodiment of the present invention includes a child-resistant package for a product comprising a film blister layer, a rupturable layer disposed adjacent the film blister layer, the rupturable layer and the film blister layer together defining at least one cavity, a

diaphragm layer having at least one slit corresponding to the at least one cavity in the film blister layer, the diaphragm layer disposed adjacent the rupturable layer on a side of the rupturable layer opposite the film blister layer, and a backing layer having at least one moveable tab corresponding to the at least one slit in the diaphragm layer, the backing layer disposed adjacent the diaphragm layer on a side of the diaphragm layer opposite the rupturable layer.

[0008] Also included as a part of the invention is a method for forming a child-resistant package for a product. The method comprises the steps of: (a) placing a product in a cavity formed in a blister cover, (b) disposing a barrier adjacent the blister cover, thereby containing the product between the blister cover and the barrier, (c) disposing a diaphragm layer adjacent the barrier layer, the diaphragm layer having at least one slit corresponding to the at least one cavity; and (d) disposing a backing layer adjacent the diaphragm layer, the backing layer having at least one peel-away tab corresponding to the at least one slit of the diaphragm layer.

[0009] In a more preferred method, the method comprises the steps of: (a) sealing a plurality dosages between a foil layer and a blister layer, (b) adhering a diaphragm layer to the foil layer such that slits in the diaphragm correspond to dosages sealed between the foil and blister layers, and (c) adhering a backing layer to the diaphragm layer such that a moveable tab in the backing layer corresponds to each slit in the diaphragm layer.

BRIEF DESCRIPTION OF THE FIGURES

[0010] The features of the invention believed to be novel and the elements characteristic of the invention are set forth with particularity in the appended claims. The figures are for illustration purposes only and are not drawn to scale. The invention itself, however, both as to organization and method of operation, may best be understood by reference to the detailed description that follows taken in conjunction with the accompanying drawings in which:

[0011] **FIG. 1** is a cross-sectional side view of a portion of one embodiment of the present invention which includes an optional card layer on top; and

[0012] **FIG. 2** is an expanded view of the embodiment shown in **FIG. 1** but without the optional card layer.

DETAILED DESCRIPTION OF THE INVENTION

[0013] The present invention includes child-resistant packages and methods for packaging dose form products. Generally, the packages according to the present invention are formed with a plurality of layers for the packaging of dosed products within a blister or other compartment formed between two of the layers. The products which can be packaged in accordance with the present invention include many types, most notably dose form products such as pharmaceuticals in pill or capsule form. Other products to which the present invention can be applied include, without limitation, medicaments (in pill, tablet, capsule, or lozenge form), drugs, vitamins, cosmetics, foods, nutraceutical products, pharmaceutical products, devices, and any other product for which dose-form consumption, or use, is desired.

[0014] This invention will now be described with reference to specific embodiments selected for illustration in the

figures. It will be appreciated that the spirit and scope of this invention is not limited to the embodiments selected for illustration. Instead, the scope of this invention is defined separately in the appended claims. Also, it will be appreciated that the drawings are not rendered to any particular proportion or scale.

[0015] The package of the present invention is formed in layers. For example, FIG. 1 shows a partial cross-sectional view of a package 10 that accommodates a dose in each of a plurality of blister cavities 12. The package is formed by layers 14, 18, 22, 26, and optionally 30, bonded to one another by one or more adhesives 16, 20, 24, and 28. More specifically, backing layer 14 is disposed against diaphragm layer 18, which in turn is disposed adjacent a rupturable layer 22 made of foil, paper, or foil-paper laminate, which in turn is disposed adjacent blister layer 26. Backing layer 14 is preferably a paper, plastic, foil or polymer backing layer that is bonded to diaphragm layer 18 by an adhesive 16. In turn, diaphragm layer 18 is bonded to rupturable 22 by an adhesive 20. In turn, rupturable layer 22 is bonded to a blister layer 26 by an adhesive 24. Finally, blister layer 26 is optionally bonded to an optional card layer 30 by an adhesive 28. This optional card layer 30 would preferably include printed indicia or information, such as advertising or dosage instructions, among other pieces of information. A preferred optional card layer is one provided by Permalith, Inc. under its mark, Permapack.

[0016] Referring to FIG. 2, package 10 is shown in an exploded view. The first component is an assembly of rupturable layer 22 and blister layer 26 having a plurality of blister cavities 12. FIG. 2 shows these two layers already adhered to each other with a suitable adhesive (including but not limited to pressure sensitive, heat activated or ultrasonic weldable type adhesives as discussed in more detail below). Optional card layer 30 is not shown in this embodiment. Assemblies of card layer 30 and blister layer 26 and rupturable layer 22 are available from Permalith Plastics, LLC of Pennsauken, N.J., under the mark PERMAPACK.

[0017] The assembly of layers 22 and 26 can contain a dose in each cavity 12. However, additional layers, as discussed below, prevent the inadvertent removal of a dose from each cavity 12 which could occur by simply pressing against the blister layer 26 and forcing a dose through a tear thus created in the paper or foil layer 22. It is the remaining layers, in conjunction with rupturable layer 22 and blister layer 26, which together provide package 10 with child-resistant features according to this invention.

[0018] Disposed below rupturable layer 22, and adjacent to rupturable layer 22, is diaphragm layer 18. Diaphragm layer 18 is adhered to rupturable layer 22 with a suitable adhesive (discussed in more detail below). Diaphragm layer 18 helps to resist the removal of a dose from a blister cavity 12, but does not unduly prevent a removal, either. Specifically, diaphragm layer 18 includes a plurality of weakened portions for resisting passage of doses therethrough. Diaphragm layer 18 is one exemplary embodiment of means for resisting passage. Alternatively, such means can be any structure capable of resisting passage and can include a slit, a perforation, a slot, or any other weakened portion capable of resisting dose removal without preventing such removal.

[0019] In the embodiments shown in FIGS. 1 and 2, for example, slits 19 are illustrated, each of which is positioned to correspond with a blister cavity 12 of the blister layer 26. Slits 19 in diaphragm layer 18 allow the passage of a dose when a user pushes on a blister cavity 12 and little or no resistance is felt on the side of diaphragm layer 18 opposite rupturable layer 22. In other words, slits 19 allow passage of a dose when the side of the slit opposite the dose side is substantially unobstructed. When diaphragm layer 18 is supported by backing layer 14, however, diaphragm layer 18, even with slits 19, provides significant resistance to the passage of the dose.

[0020] Backing layer 14 is provided beneath diaphragm layer 18 and is attached to diaphragm layer 18 with a suitable adhesive (discussed in more detail below). Backing layer 14 has a plurality of tabs 15, each of which is positioned to correspond to a slit 19 of diaphragm layer 18 and a blister cavity 12 of blister layer 26. Each tab 15 of backing layer 14 preferably includes a perforated portion 15A to permit at least partial removal of the tab 15 from backing layer 14. Also preferably on tab 15 is a fingernail slot 15B to provide fingernail access for movement of the tab 15 with respect to backing layer 14. Any specific means of tab removal, however, is envisioned as within the scope of the present invention for backing layer 14.

[0021] Blister layer 26 can be made from any suitable blister layer material known to those skilled in the art, and is preferably a clear or opaque plastic or foil type material. Exemplary materials include transparent or translucent thermoformable materials such as polyvinyl chloride or polystyrene. Rupturable layer 22 is made from any suitable paper, foil-paper combination or foil material known to those skilled in the art, and is preferably foil. This layer is preferably capable of ripping or otherwise tearing so as to allow removal of the dose. Diaphragm layer 18 can be formed from a plastic or paper material. Optionally, it is formed from a plastic material such as TYVEK (Tyvek is a registered trademark of E. I. du Pont de Nemours and Company for non-woven barrier material), or another material that has relatively increased tear strength and puncture resistance. Similarly, backing layer 14 can be formed from such paper, plastic, foil, polymers or laminates thereof.

[0022] The adhesives used to join the different layers of this invention as discussed above include any suitable adhesives which are acceptable for the dosage which is contained therein. Typically the dosage is a human pharmacological product, although the invention is not limited thereto. Federal regulations provide for suitable pharmaceutical packaging adhesives, as delineated in 21 C.F.R. § 175.105.

[0023] In use, a user of the package 10 lifts a tab 15 from backing layer 14 using a fingernail or fingertip. The tab 15 lifted is either completely removed or is left hanging. The user can then push against the top of a blister cavity 12 on blister layer 26 in order to push a dose from the blister cavity 12 through rupturable layer 22, through slit 19 of diaphragm layer 18 and out through the backing layer 14 at a location where the tab 15 has been removed.

[0024] By requiring the sequential step of removing a tab 15 before pushing out the dose corresponding to that par-

particular removed tab, the present invention provides a child-resistant package while not requiring much dexterity or force. This latter feature is important in that it provides a physically, relatively easy means of accessing a dose, which is preferable for seniors and others having any type of dexterity or strength problem, while still preventing children from improperly accessing the dose.

[0025] Also included as a part of the invention is a method for forming a child-resistant package for a product. The method comprises the steps of: (a) placing a product in a cavity formed in a blister cover, (b) disposing a barrier adjacent the blister cover, thereby containing the product between the blister cover and the barrier, (c) disposing a diaphragm layer adjacent the barrier layer, the diaphragm layer having at least one slit corresponding to the at least one cavity; and (d) disposing a backing layer adjacent the diaphragm layer, the backing layer having at least one peel-away tab corresponding to the at least one slit of the diaphragm layer.

[0026] In a more preferred method, the method comprises the steps of: (a) sealing a plurality of dosages between a foil layer and a blister layer, (b) adhering a diaphragm layer to the foil layer such that slits in the diaphragm correspond to dosages sealed between the foil and blister layers, and (c) adhering a backing layer to the diaphragm layer such that a moveable tab in the backing layer corresponds to each slit in the diaphragm layer.

[0027] Although the invention is illustrated and described herein with reference to specific embodiments, the invention is not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the invention. Such modifications could include those noted above, such as the use of an optional cover card, or even additional other layers not mentioned.

What is claimed:

1. A child-resistant package for a product comprising:
 - a blister layer;
 - a rupturable layer disposed adjacent the blister layer, said rupturable layer and said blister layer together defining at least one cavity;
 - means for resisting passage of a dose, said means disposed adjacent said rupturable layer on a side of said rupturable layer opposite said blister layer; and
 - a backing layer having at least one moveable tab corresponding to said at least one cavity, said backing layer disposed adjacent said means for resisting on a side of said means opposite said rupturable layer.
2. The child-resistant package of claim 1 wherein said means for resisting is a diaphragm layer having a slit disposed therein.
3. The child-resistant package of claim 1 wherein said means for resisting is comprised of plastic.
4. The child-resistant package of claim 1 wherein said backing layer comprises paper.
5. The child-resistant package of claim 1 wherein said rupturable layer comprises foil.

6. The child-resistant package of claim 1 wherein said backing layer comprises plastic.

7. The child-resistant package of claim 1 wherein said means for resisting is a diaphragm layer formed of a non-woven barrier material.

8. The child-resistant package of claim 1 wherein said backing layer is formed of a non-woven barrier material.

9. The child-resistant package of claim 1 wherein said rupturable layer is formed of a woven barrier material.

10. A child-resistant package for a product comprising:

a blister layer;

a rupturable layer disposed adjacent the blister layer, said rupturable layer and said blister layer together defining at least one cavity;

a diaphragm layer having at least one slit corresponding to the at least one cavity in said blister layer, said diaphragm layer disposed adjacent said rupturable layer on a side of said rupturable layer opposite said blister layer; and

a backing layer having at least one moveable tab corresponding to the at least one slit in said diaphragm layer, said backing layer disposed adjacent said diaphragm layer on a side of said diaphragm layer opposite said rupturable layer.

11. The child-resistant package of claim 10 wherein said diaphragm layer comprises paper.

12. The child-resistant package of claim 10 wherein said backing layer comprises paper.

13. The child-resistant package of claim 10 wherein said diaphragm layer comprises plastic.

14. The child-resistant package of claim 10 wherein said rupturable layer comprises foil.

15. The child-resistant package of claim 10 wherein said backing layer is plastic.

16. The child-resistant package of claim 10 wherein said diaphragm layer is formed of a non-woven barrier material.

17. The child-resistant package of claim 10 wherein said diaphragm layer is formed of a woven barrier material.

18. The child-resistant package of claim 10 wherein said backing layer is formed of a non-woven barrier material.

19. A method for forming a child-resistant package for a product, said method comprising the steps of:

(a) placing a product in a cavity formed in a blister cover;

(b) disposing a barrier adjacent the blister cover, thereby containing the product between the blister cover and the barrier;

(c) disposing a diaphragm layer adjacent the barrier layer, said diaphragm layer having at least one slit corresponding to the at least one cavity; and

(d) disposing a backing layer adjacent the diaphragm layer, said backing layer having at least one peel-away tab corresponding to the at least one slit of the diaphragm layer.

20. The method of claim 19 wherein step (b) comprises disposing a foil layer adjacent the blister cover.

21. The method of claim 19 wherein step (c) comprises disposing a plastic layer adjacent the barrier layer.

22. The method of claim 19 wherein the backing is formed from any one or more of film, plastic, non-woven barrier material, woven barrier material or paper.

23. A method of packaging a dosed product comprising the steps of:

(a) sealing a plurality dosages between a foil layer and a blister layer;

(b) adhering a diaphragm layer to the foil layer such that slits in the diaphragm correspond to dosages sealed between the foil and blister layers; and

(c) adhering a backing layer to the diaphragm layer such that a moveable tab in the backing layer corresponds to each slit in the diaphragm layer.

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