(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 771 737 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
07.05.1997 Bulletin 1997/19

(51) Int Cl.[6]: **B65D 75/34**, B65D 75/58

(21) Application number: **96307834.0**

(22) Date of filing: **30.10.1996**

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB IE IT LI NL PT SE

(30) Priority: **31.10.1995 US 550901**

(71) Applicant: **McNEIL-PPC, INC.**
Skillman, NJ 08558 (US)

(72) Inventor: **Fuller, Kenneth E.**
Lansdale, Pennsylvania 19446 (US)

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

(54) Blister pill package with safety backing

(57) A non-through score cut (14) is made in the exposed surface of the blister forming sheet (15). The non-through score cut is made from one edge of an individual blister unit (13) to an opposite or adjacent edge. When the blister unit is angulated or flexed back at the non-through score cut, the blister forming sheet will fracture. The smaller portion of the fractured forming sheet, still bonded to the backing material, acts as a tab (20) for peeling the backing sheet (25) from the forming sheet exposing the blister contents.

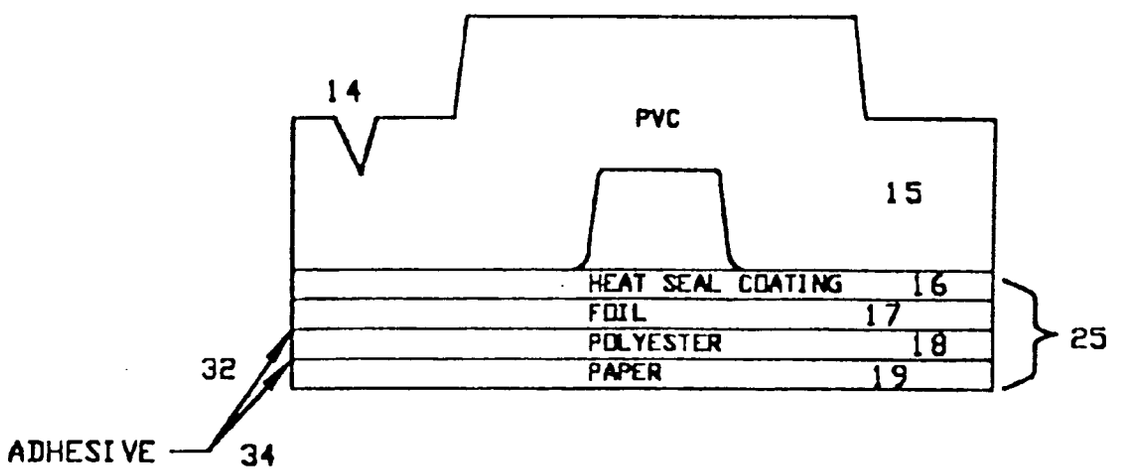

FIGURE 4

EP 0 771 737 A1

Description

BACKGROUND OF THE INVENTION

The present invention relates to a safety blister-type package for enclosing medication or pills.

As disclosed in U.S. Patent No. 3,809,211, one of the problems facing today's parents is in keeping medication or pills beyond the reach of their children. Children do not have the ability to recognize the risk involved in consuming unprescribed medication. Because of this fact there is an urgent need for a package from which pills are readily accessible to the adult, but not accessible to the child.

Press-through packs or "blister" packs are commonly used today to package units of medication or pills for oral ingestion. The press-through package is made up of a first sheet, typically a clear, performed polyvinyl chloride or polystyrene with flexible bubbles which form separate compartments for one or more pills; and a second rupturable sheet material, like an aluminum foil or paper sheet, which has been attached to the first sheet. The metal foil is attached by heat-sealing, solvent welding, gluing, or otherwise adhering the foil sheet to the blister sheet. The tablet is removed from the blister compartments by pressing on the flexible blister which in turn forces the tablet against the foil, rupturing the foil, and ejecting the tablet.

It is sometimes desirable in making such a press-through package to include between the first and second sheets a rigid tray in which there are holes while coincide with the blisters in said first sheet. The rigid tray is used to protect the pills from contamination and mechanical damage and may contain printed instructions as to the type of pill or the time a particular dosage is to be taken and with an indication of the dosage that has already been taken.

The recent trend in the packaging of medication has been to provide packages which will be safe, even if found by children. Most developments in the "child-resistant" line have been directed to the improvement in pill bottles. In this regard, safety caps have been devised which require a certain series of pushes and turns in order to open the bottle. However, there has been little development in the area of "child-resistant" press-type blister packages with which this invention is concerned.

Packages which have used more than one backing layer on a press-through blister-type package have not used a layer of backing material which cannot be ruptured. The prior backing layers which have been used to cover the rupturable layer, have been made from paper or foil and may have been scored or weakened so that all backing layers can be ruptured to press a pill through the package. These additional prior art backing layers have been used for the purposes of providing printed information on the back of the pill package and for additional sealing engagement to protect the pills from the environment. For example, see the following U.S. Patent Nos.: Nagy, 3,503,493; Osborn, 3,621,992; Sorensen, 2,317,860; and Heller, 3,387,699. In each of these patents the multiple backing layers used on the blister or press-through type pill package can be easily ruptured or peels away and are not strong enough to provide "child-resistancy".

One attempt at providing a "resistancy" blister-type pill package, can be seen in the Helstrom U.S. Patent No. 3,472,368. In this patent, there is no second backing member which is peeled away to expose the rupturable layer as will be disclosed in describing the present invention. This package is supposedly "child-resistant" simply by providing a rupturable sheet which is very difficulty ruptured. The Helstrom patent, therefore, relies on the child's weakness as the necessary element to prevent him from opening the package.

In, Compere, U.S. Patent No. 3,921,805, the concept is to provide a pill package which requires knowledge of the package opening procedure rather than a minimum amount of strength for opening said package. The person who is likely to be taking pills is not generally in a very strong physical condition. Quite often, the strength of a child is greater than the strength of the person who is ill and most likely to be taking pills. Because of this fact, this invention was developed to provide a pill package which can be opening by the instructed adult who may have no more strength than the average child. The child who is uninstructed on the opening of the herein disclosed package will not be able to reach the package contents. The present invention, therefore, relies on the superior knowledge of the adult rather than his superior strength in order to make a package which is easily opened by the adult but cannot be opened by the child.

FIELD OF THE INVENTION

A primary object of the present invention is to provide a "child-resistant" pill package which can be easily opened by one who has been given instructions on how to do so, but cannot be opened by the uninstructed child.

Another object of the present invention is to provide a pill package which, when opened, makes only one dosage of pills accessible to the user, which dosage, of course, is less than a lethal dosage.

Another object of the present invention is to provide a pill package in which any desired number of pills can be made accessible upon opening.

Another object of the present invention is to provide a pill package in which one pill or one dosage of pills can be removed from the package while the remaining pills can be maintained in an air-tight enclosure.

Another object of the present invention is to provide a pill package in which the use of cumbersome bottles is not required.

Another object of the present invention is to provide a pill package in which each individually pill can be separately packaged so that the desired dosage can be car-

ried by the user without the necessity of carrying excess pills.

Another object of the present invention is to provide a pill package which requires additional package opening to remove each additional pill.

Another object of the present invention is to provide a safety pill package which children, an average, cannot open without the aid of tools.

Yet another object of the present invention is to provide a pill package in which opening of the package makes accessible fewer than a dangerous number of units of medication. The number of units exposed upon each opening of the package can be varied depending upon the toxicity of the packaged medication.

The present invention is concerned with a blister package which is similar to the common blister package, but which has a strong flexible backing sheet which encloses each blister. The strong flexible backing sheet is secured to the back of the blister sheet in such a manner that when secured, the backing sheet is not pushed away from the blister sheet when pressure is put on the blister-side of the pill package in an attempt to push the pill through the package. For the user to be able to remove a pill form the package, the strong backing sheet must first be peeled away. So long as the required adherence is obtained, the strong backing sheet must first be peeled away. So long as the required adherence is obtained, the strong backing sheet can be secured to the blister sheet by heat sealing, solvent welding, gluing or otherwise adhering the two sheets together. A preferred method is by heat-sealing.

There are hundreds of heat-sealed coating formulations which can be used to provide heat-sealability between the layers of the package laminate of the present invention. These heat-seal formulations are commonly used in making foil/paper and resin sheet/resin sheet laminates for soap wraps, carton overwraps, cereal liners, cookie wraps, and other uses. The heat-seal formulations are typically a water dispersion of a vinyl resin or a vinyl resin containing wax for providing lower heat-sealing temperatures. The vinyl resin can be ion-linked and acid-modified ethylene interpolymers known as ionomer resins. Was and other modifiers further extend the range of performance properties.

The preferred heat-seal formulations are water dispersions of ethylene interpolymers - for example ethylene/vinyl acetate interpolymers. The vinyl resin formulations combine broad adhesion properties with moderate hot tack. Modifiers such as pigments, waxes or other resins can be used.

It is preferred to apply the heat-seal coatings in an amount of about 7 grams/meter^2. The coatings can be applied by common methods, for example, curtain coating or roller coatings as known in the art.

The blister sheet is made in a known manner and is made from common blister sheet material such as polyvinyl chloride, and copolymers and terpolymers of vinyl chloride, and copolymers and terpolymers of vinyl chloride, for example the terpolymer of polyvinyl chloride/polyethylene/polypropylene.

The backing sheet should have a layer or sheet of a strong flexible polymeric material of sufficient strength that a pill cannot be hand-forced through the polymeric material. A sheet of polyester material has been found to have sufficient strength to prevent a pill from being forced therethrough. A preferred polyester material is polyethylene terephthalate.

A foil sheet can also be used as part of the backing sheet if a barrier resistance coating is needed to prevent moisture from penetrating into the blister. A metal foil, such as aluminum, having a thickness as small as 0.0008 inch is sufficient.

A sheet of paper for the purpose of printing may also form part of the backing sheet. Bleached kraft paper having a basis weight of roughly 30 pounds is preferred. Dates, numbers, or a description of the package contents can be printed on the paper for consumer information.

The various layers comprising the backing sheet can be laminated to form a single laminated sheet prior to applying the backing sheet to the blister sheet, or the backing layers can be secured together at the same time they are adhered to the blister sheet. The preferred method of laminating is by using heat-seal coatings, as previously described. It is usually desirable to provide a paper sheet as the sheet farthest from the blister sheet so that printing is easily read from the bottom or non-blister side of the package. However, if it is not necessary to prevent moisture penetration into the blister, the printed paper can be positioned next to the transparent blister sheet and read through the blister sheet from the top of the package.

The strong polymeric sheet, foil sheet, and paper can be applied to the blister sheet in any order except that the paper sheet cannot be positioned next to the blister sheet if it is necessary to prevent moisture from entering the blister. Thus, the strong polymeric sheet can be positioned next to the blister sheet or intermediate between the foil and paper sheet, or as the sheet farthest from the blister. If the paper sheet is between the foil and strong polymeric sheet, the polymeric sheet would have to be transparent so that printing on the paper can be read by the consumer.

When applied as a single lamination structure, the layers of the backing sheet can be secured together by heat-sealing, solvent welding, gluing, applying sheets of adhesive materials between the layers, or otherwise adhering the layers together. For example, a sheet of extruded polyethylene can be included between the sheet of strong flexible material and the foil sheet and likewise between the foil and paper sheet. The extruded polyethylene will adhere the three sheets together upon the application of pressure without the necessity of heat-sealing. It is preferred to use an extruded polyethylene sheet or film. Heat-seal coatings can be used in addition to intermediate adhesive layers.

After securing the blister sheet to the backing sheet, the backing sheet cannot be forced to disengage the blister sheet by applying pressure on the pill from the blister-side of the packet. However, the backing sheet can readily be peeled from the back of the package so that the blister contents can be removed. The seal between the blister sheet and backing sheet must be strong enough so that when pressure is applied to the blister, the flexible backing sheet remains in contact with the blister sheet. The backing must be strong enough so that with the backing sheet engaged, a pill cannot be forced through the backing sheet by applying pressure to the pill from the blister-side of said package.

A strong polyester which has been found particularly effective as at least one component of the backing sheet is polyethylene terephthalate. The thickness of the polyester is preferably about 48 gauge. This gauge also helps prevent biting of the package. However, any plastic with strength sufficient to prevent a pill from being hand-forced therethrough can be used for this purpose.

A "non-through" score cut is made in the exposed surface of the blister forming sheet. The non-through score cut is made from one edge of an individual blister unit to an opposite or adjacent edge. When the blister unit is angulated or flexed at the non-through score cut, the blister forming sheet will fracture. The smaller portion of the fractured forming sheet, still bonded to the backing material, acts as a tab for peeling the backing sheet from the forming sheet, exposing the blister contents.

The depth of the non-through score cut into the blister forming sheet is critical for producing an effective package. A non-through score cut of minimal depth will produce a more effective child resistant package than that with a deeper cut and a non-through score cut of maximum depth will produce a more effective senior adult use package than that with a lesser cut. An effective score cut depth is required to produce a package that is both child resistant and senior effective for a given product toxicity level.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The invention together with the above and other objects may be best understood from a consideration of the following detailed description of an illustrative embodiment in the course of which reference is had to the accompanying drawings in which:

Figure 1 is a plan view of the safety blister package (card) of the present invention showing multiple individual blister units in one package;

Figure 2 is a perspective view of one of the individual blister units shown in Figure 1;

Figure 3 is a perspective view of one of the individual blister units of Figure 1 in which the blister unit is partially opened; and

Figure 4 is an enlarged fragmentary cross section illustrating the various layers, adhesives, and unsealed areas.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings and first to Figure 1, a safety blister package is indicated as a whole by the reference character 10. The package 10 may contain multiple individual blister units 13 having only one single or double cavity 11 of any desired shape which conform to the shape of the particular medicament or pill contained within said blister. The individual blister units 13 can be separated from each other by tearing the package at the perforated cut lines 12. Across one corner of each individual blister unit 13, a non-through score line 14 is cut into the forming sheet 15 providing an opening feature for each individual blister unit 13. When the corner of each individual blister unit 13 is angulated or flexed along the non-through score cut line 14, the forming sheet 15 is broken along that score cut line 14.

Backing sheet 25 as shown in Figure 4 contain a heat seal coating 16, a foil barrier sheet 17, a sheet of a strong flexible polymeric material for example a polyester such as polyethylene terephthalate 18, and a paper sheet 19 which can have printing thereon to convey information to the consumer such as the package contents and package opening instructions. Figure 2 and Figure 3 shows tab 20 which is formed by angulating or flexing the corner of the individual blister unit along the non-through score cut 14 as explained above.

As previously set forth, the backing sheet 25 need not contain all three layers of foil, strong flexible polymeric material and paper. However, the strong polymeric material is necessary for the purpose of providing a safety backing to the blister sheet 15 so that the pills cannot be forced out of the package without first peeling the backing sheet 25 from the blister sheet 15.

The heat seal coating 16 is typically extruded onto the foil layer 17. Figure 4 shows one embodiment of adhering the foil, strong flexible polymeric material, and paper layer (i.e. backing material 25) to the blister forming material 15. This heat seal coating layer 16 is heated and with pressure applied, bonds to the blister forming material 15. The layers 17, 18, and 19 of the backing sheet 25 can be secured together by heat sealing, solvent welding, gluing, applying sheets of adhesive materials between the layers, or otherwise adhering the layers together. Figure 4 shows one embodiment of adhering the foil, strong flexible polymeric material, and paper layers together by means of adhesive layers 32 and 34.

While the present invention has been described with reference to a medicament or pill, it can also be used to make a child-resistant package for capsules, tablets, suppositories, etc.

It is believed that there are significant differences making this concept more cognitive, more child resistant, and potentially easier to open for the senior adults then, for instance Compere '805. Those differences include:

1. Child Resistant - Children tend to focus their attention on areas of difference (i.e. protrusions, unsealed areas) on the cavity or "pill" side of the blister unit. If there is no areas of difference, children will randomly pick at and bend the blister unit.

a. there are no apparent areas of difference

1. there are no protrusions
2. there are no accessible unsealed areas
3. the score cut line is nearly invisible to the child, partially due to being "camouflaged" by a cross hatch pattern by the seal.

b. the opening feature is robust for random aggressive handling

1. the score cut depth is minimized
2. the score cut is optimally positioned (corner cut)

2. Ease of Opening - Senior adults will not have to rely on physical force to open package

a. the bending and breaking of the tab will require minimal force (dependent on child access)
b. the peel strength of the backing material will be minimal. If the bending task is not apparent to the children, the seal strength of the backing material to the forming material can be reduced.

3. Cognitive - Senior adults will have to rely on cognitive skills rather than physical force to open this package. If the multiple step opening instructions are well communicated, the seniors will be able to access the contents of the package effectively where as the children will not.

Claims

1. A protective childproof package comprising:

a first sheet having one or more flexible blisters which form compartments, each blister being adapted to receive a medicament;
a backing sheet closing and sealing the compartments formed by the blisters in the first sheet and being secured to the first sheet along each edge of said first sheet and over substantially the entire backing sheet surface area except at each blister;
said backing sheet secured to said first sheet such that said backing sheet cannot be forced out of engagement with said first sheet when force is applied to said first flexible blisters; and
said backing sheet having at least one sheet of material therein which has sufficient strength so that the backing sheet can neither be ruptured nor forced out of engagement with the first sheet when force is applied to the medicament from the blister side of the package said backing sheet further having a line of weakening along one of its edges.

2. A protective childproof package as defined by claim 1 wherein the first sheet is secured to the backing sheet with a heat seal coating.

3. A protective childproof package comprising:

a first sheet having one or more flexible blisters which form compartments, each blister being adapted to receive medicament;
a backing sheet closing and sealing the compartments formed by the blisters in the first sheet and being secured to the first sheet along each edge of said first sheet and over substantially the entire backing sheet surface area except at each blister;
said backing sheet secured to said first sheet such that said backing sheet cannot be forced out of engagement with said first sheet when force is applied to said flexible blisters;
said backing sheet having at least one sheet of material therein which has sufficient strength so that the backing sheet can neither be ruptured nor forced out of engagement with the first sheet when force is applied to the medicament from the blister side of the package said backing sheet further having a line of weakening along one of its edges and said blister holding at least one pill dosage.

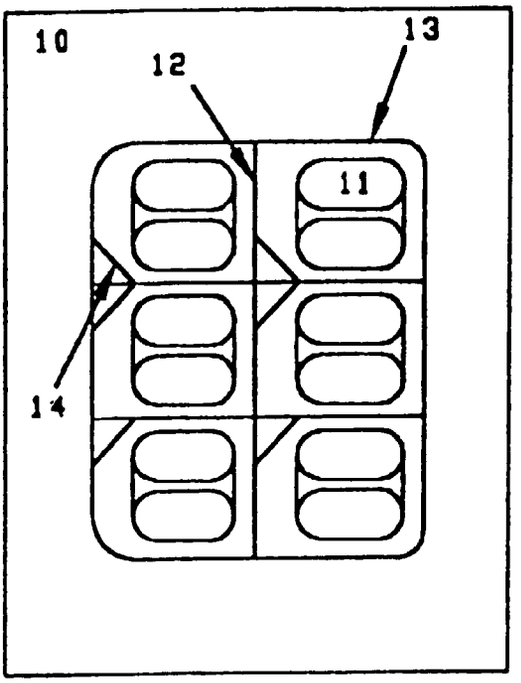

FIGURE 1

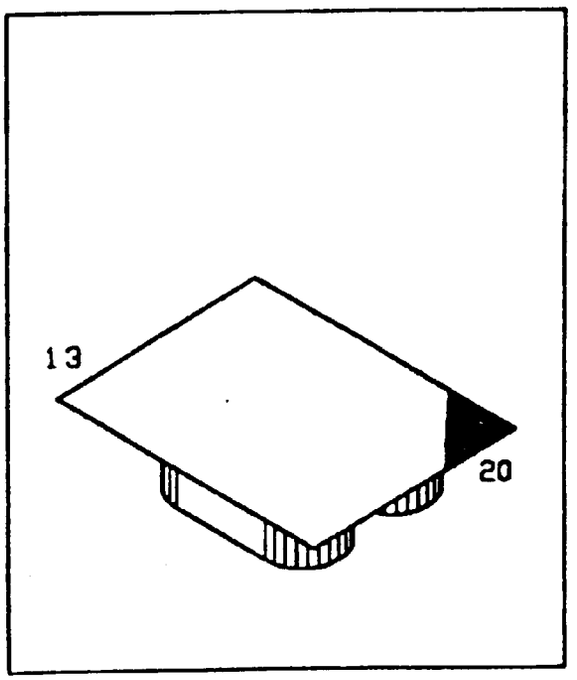

FIGURE 2

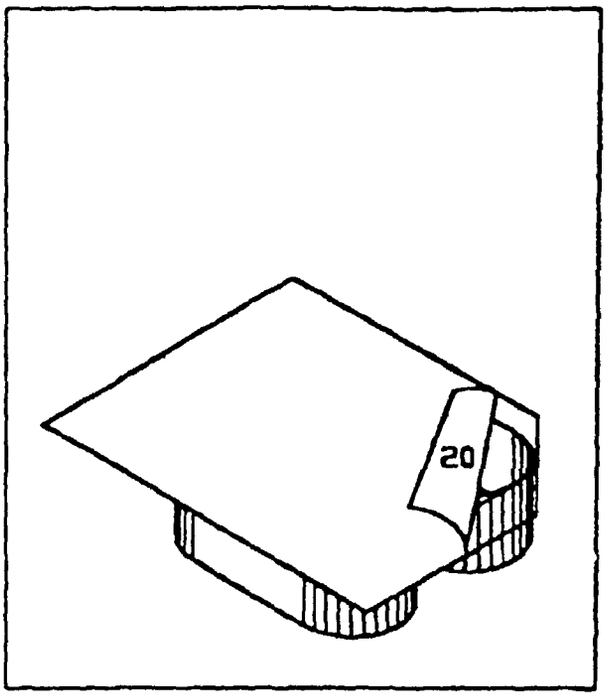

FIGURE 3

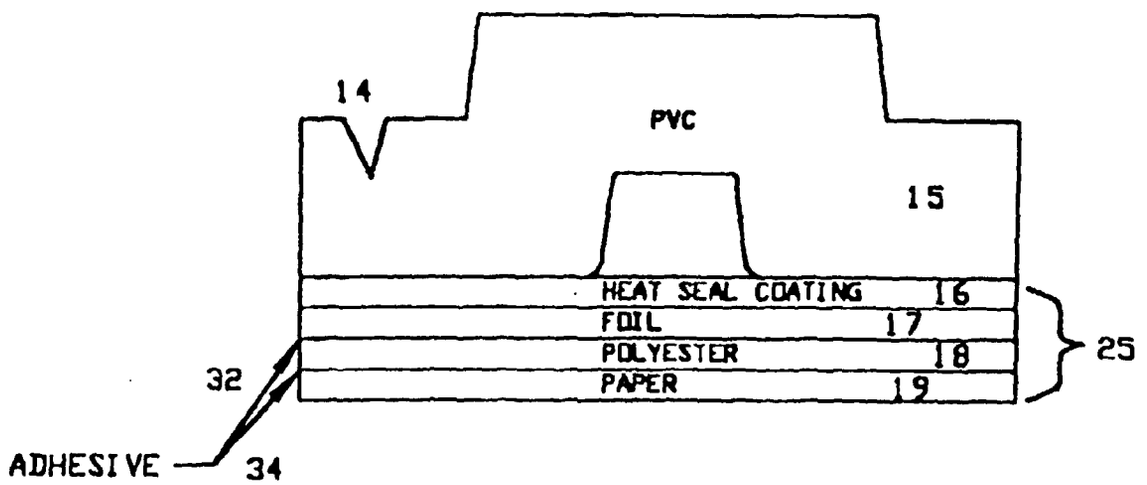

FIGURE 4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 30 7834

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.6)
X,D	US 3 809 221 A (COMPERE) * the whole document *	1,3	B65D75/34 B65D75/58
X	FR 2 227 190 A (ALUMINIUM SUISSE) * the whole document *	1,3	
X	US 3 924 746 A (HAINES) * the whole document *	1,3	
X	US 3 912 081 A (HAINES ET AL.) * the whole document *	1,3	
X,P	US 5 469 968 A (MATTHEWS ET AL.) * the whole document *	1,3	
A	US 4 243 144 A (MARGULIES)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

B65D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	21 February 1997	Gino, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)