Nov. 2, 1954 W. C. WARD 2,693,438

PREFORMED, NONADHERENT FILMS FOR APPLICATION TO OPEN LESIONS

Filed Feb. 21, 1951

Fig. 1.

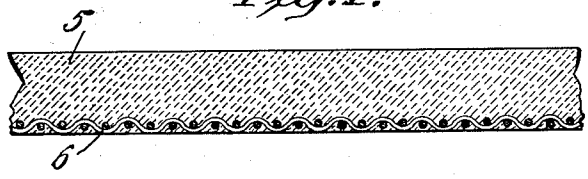
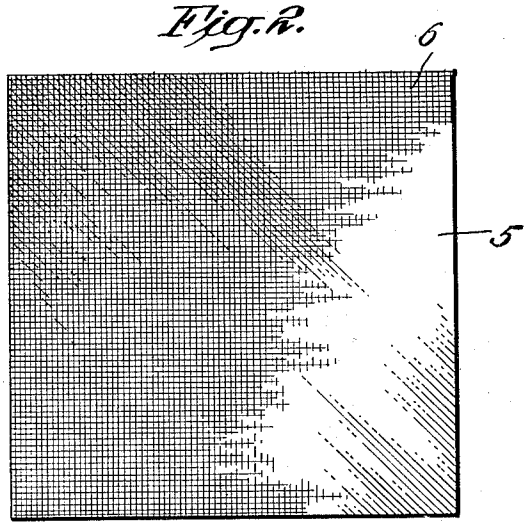


Fig. 2.



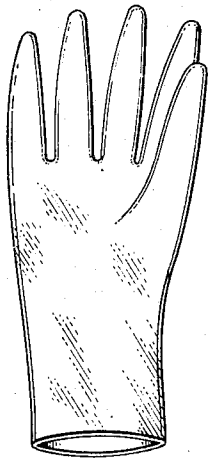


Fig. 3.

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PREFORMED, NONADHERENT FILMS FOR APPLICATION TO OPEN LESIONS

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20 Claims. (Cl. 167—84)

This invention relates to surgical dressings and aims to provide an improved preformed, non-adherent film for application to open lesions.

In the past treatment of open lesions such as are caused by burns, wounds and the like, the dressings which have been applied thereto to supply medication or to serve as a protection against infection have frequently interfered with the rapid healing of the wound. When an ordinary dressing is applied to a moist lesion, the scab or granulation tissue formed at the surface of the lesion frequently becomes incorporated with the dressing so that the scab or new skin forming during the healing process may be pulled away when the dressing is removed, causing secondary hemorrhage.

A further disadvantage of past dressings has resulted from the fact that when a medicament has been required in the treatment of an open lesion, it has been necessary to apply a fresh dressing to the lesion at frequent intervals, usually as often as at least once each day to replenish the medicament, resulting in disturbance and irritation of the lesion. Attempts have been made to overcome these disadvantages which are inherent in ordinary surgical dressings through the use of non-fibrous films. However, such films have been so stiff and harsh that they could not conform evenly to the surface of the lesion and they have had an irritating effect thereon which was not conducive to speedy healing.

I have discovered that it is possible to prepare a soft, pliant film which can be applied evenly to the surface of a moist lesion, and which will not irritate the lesion or become incorporated with a scab or granulation tissue formed therein, by modifying a quantity of solid water-soluble polyvinyl alcohol with a much larger quantity of an appropriate plasticizing agent and a quantity of water. The film so formed also possesses sufficient coherence to provide a resilient support when used as a dressing and to permit of its being molded to conform with the contour of a part of the body, such as a hand. The film can be sterilized before use by autoclaving in known manner without sacrifice of its qualities of softness and pliancy and, when it is applied to a moist, open lesion, there is produced between the wound tissue and the outer dressing a continuous liquid phase which prevents the outer dressing from adhering or becoming stuck to the wound tissue in such a manner that the wound might be further traumatized upon removal of the dressing.

It is a particular feature of my invention that I may incorporate in the non-adherent film a chemotherapeutic agent which is slowly released from the film in a form in which it is miscible with the body fluids in an effective quantity, thereby obviating the necessity for frequent changes of the dressing of a wound which requires medication. It is a further and important feature of my invention that the soft, pliant, non-adherent film can be reinforced by embedding a textile material in the outer surface thereof.

A preformed, non-adherent film prepared in accordance with my invention comprises about 3 parts of a polyvinyl alcohol of a grade which is at least 76% hydrolyzed and is preferably of a grade which is about 98.5–100% hydrolyzed, and about 30 to about 35 parts of a plasticizing agent consisting of polyethylene glycol having a molecular weight between about 200 and about 400, or propylene glycol or a mixture of the two and about 4 parts at least of water. When the film is designed for treatment of a lesion requiring medication, about 0.1 part of an antibacterial nitrofuran is incorporated therein.

The film is ordinarily cast in the form of flat strips or sheets which may be cut into strips. However, it can, if desired, be molded in the form of a glove, for instance, which can then be used as a dressing for a serious burn of the hand and fingers.

In order that my invention will be clear to those skilled in the art, I will describe the mode of practicing it which I now prefer with reference to the accompanying drawings in which:

Fig. 1 is a transverse section, greatly enlarged, of a portion of reinforced film embodying my invention;

Fig. 2 is an enlarged plan view of a piece of reinforced film embodying my invention; and

Fig. 3 is a perspective view of a non-adherent film embodying my invention and molded to fit over a human hand.

At the present time there are four different commercial grades of polyvinyl alcohol which can be used in the practice of my invention. The one which I prefer to use is marketed by E. I. du Pont de Nemours & Company under the trade name "Elvanol 72—51" and is a grade which is 98.5–100% hydrolyzed, i. e., it contains not more than about 1.5% of non-hydrolyzed polyvinyl acetate. The other polyvinyl alcohols which can be used in the practice of my invention are also marketed by the Du Pont Company under the trade names "Elvanol 51—05" (a grade which is 86–89% hydrolyzed), "Elvanol 54—22" (a grade which is 91–93% hydrolyzed) and "Elvanol 31—31" (a grade which is 76–79% hydrolyzed).

The chemotherapeutic agents with which I obtain the best results in preparing a medicated film in accordance with my invention are the antibacterially active nitrofurans, and the one which I prefer to use is 5-nitro-2-furaldehyde semicarbazone (U. S. Patent No. 2,416,234). Among other antibacterially active nitrofurans which can be used are those referred to in U. S. Patents Nos. 2,416,233; 2,416,235; 2,416,236; 2,416,237; 2,416,238 and 2,416,239. Many of these nitrofurans, including 5-nitro-2-furaldehyde semicarbazone, are only slightly soluble in water. However, I have discovered that the plasticizers which I use to modify polyvinyl alcohol in the preparation of my film are capable of dissolving an effective dosage of an antibacterially active nitrofuran. Those plasticizers are miscible with water and, in the presence of aqueous media, they and the nitrofuran dissolved therein are very slowly extracted from the film. Consequently, when my medicated film is used as a surgical dressing for a moist lesion, an effective dosage of the nitrofuran is extracted from the film and is mixed with the body fluids where it exerts its chemotherapeutic action in combating infections over an extended period of time.

The plasticizer which I prefer to use in the practice of my invention consists of a mixture of propylene glycol and polyethylene glycol which is liquid at normal room temperatures. Polyethylene glycol whose average molecular weight is around 300 gives excellent results. However, it is not essential that a mixture of those glycols be used. Propylene glycol alone or a liquid polyethylene glycol alone, if used in sufficient quantities, provides a satisfactory film. Of the two, I prefer the polyethylene glycol for, when used alone, it has a greater solvent capacity for the nitrofurans than does propylene glycol when used alone.

Example 1

(Unmedicated film)

	Parts
Polyvinyl alcohol (Elvanol 72—51)	3.0
Propylene glycol	20.0
Polyethylene glycol (average molecular weight 300)	15.0
Water	62.0

The polyvinyl alcohol is dissolved in water by heating to 85–90° C. and stirring. The propylene glycol and polyethylene glycol are then mixed and added to the aqueous polyvinyl alcohol solution. This mixture is then spread upon a drying pan and placed in an oven with circulating air held at a temperature of approximately 50° C. for about 12 hours when the pan is removed and the film is stripped therefrom.

Example 2

(Medicated film)

	Parts
Polyvinyl alcohol (Elvanol 72—51)	3.0
Propylene glycol	20.0
Polyethylene glycol (average molecular weight 300)	15.0
5-nitro-2-furaldehyde semicarbazone	0.1
Water	61.9

The nitrofuran is dissolved in the propylene glycol and polyethylene glycol and this is then added to an aqueous solution of polyvinyl alcohol prepared as described above in Example 1. The mixture is then spread upon a drying pan and placed in an oven with circulating air at a temperature of about 50° C. for 12 hours, when the pan is removed and the film is stripped therefrom. The concentration of nitrofuran due to the drying and loss of volatile portions of the original mix is in the neighborhood of 1:300. This concentration of nitrofuran is sufficient to allow a high antibacterial effect. In the preparation of a medicated film, any of the other antibacterially active nitrofurans which are referred to above may replace 5-nitro-2-furaldehyde semicarbazone.

Example 3

	Parts
Polyvinyl alcohol (Elvanol 31—31)	3.0
Propylene glycol	20.0
Polyethylene glycol (average molecular weight 300)	15.0
Water	62.0

The polyvinyl alcohol is dissolved in the water at room temperature. The propylene glycol and polyethylene glycol are then added to the aqueous polyvinyl alcohol solution after which the mixture is dried to form a film as described in Example 1. In preparing a medicated film according to this example, about 0.1 part of an antibacterially active nitrofuran is dissolved in the plasticizer as described in Example 2.

Example 4

	Parts
Polyvinyl alcohol (Elvanol 51—05)	3.0
Polyethylene glycol (average molecular weight 300)	30.0
Water	67.0

The polyvinyl alcohol is dissolved in water by heating to 85–90° C. and the polyethylene glycol is then added to this solution after which it is dried to form a film as described in Example 1. In preparing a medicated film according to this example, about 0.1 part of an antibacterially active nitrofuran is dissolved in the plasticizer as described in Example 2.

Example 5

	Parts
Polyvinyl alcohol (Elvanol 54—22)	3.0
Propylene glycol	35.0
Water	62.0

The polyvinyl alcohol is dissolved in water by heating to 85–90° C. and the propylene glycol is then added to this solution after which it is dried to form a film as described in Example 1. In preparing a medicated film according to this example, about 0.1 part of an antibacterially active nitrofuran is dissolved in the propylene glycol before that substance is admixed with the aqueous polyvinyl alcohol solution.

Example 6

The bottom of the drying pan is covered with a single thickness of strips or a sheet of thin gauze (about 44 threads per in.). An aqueous solution of polyvinyl alcohol with which a large quantity of plasticizer has been admixed, and which may contain an antibacterially active nitrofuran as described in any of the preceding examples, is then poured over this gauze and the drying pan is placed in an oven and heated at 50–55° C. for a period of approximately 5 hours, at the end of which time it will be found that the strips or sheet of gauze will be embedded in the lower surface of the film. The reinforced film is then removed from the tray and cut into strips as desired. Such a reinforced strip is illustrated in Figs. 1 and 2 wherein the soft, non-adherent film is indicated at **5** and the gauze which reinforces it is indicated at **6**. When such a reinforced film is used as a surgical dressing, the face in which the gauze **6** is embedded forms the outer surface of the dressing. The gauze is thus insulated from the wound by the non-adherent film which prevents the gauze from sticking to the wound.

Example 7

A mixture of plasticizer, which may have an antibacterially active nitrofuran dissolved therein, is added to an aqueous solution of polyvinyl alcohol as described in any of Examples 1 and 2. This mixture is then applied to the outer smooth surface of a form shaped to conform to one of the parts of the human body, such as a hand. The coated form is then placed in an oven and heated at 50–55° C. for a period of approximately 5 hours. At the end of this period it will be found that the form is covered with a film which can be stripped therefrom and which resembles a glove, as illustrated in Fig. 3 of the drawings. A film which has been formed in this manner can be used as a glove to cover the hand for example, and forms a very effective surgical dressing for a part of the body which cannot be easily covered by the surgical dressings which have been used in the past.

The terms which I have used in describing my invention are terms of description and not of limitation and it will be appreciated that various modifications may be made in the preferred embodiment which I have described without departing from my invention as it is defined in the appended claims.

What I claim is:

1. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

2. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 15 parts of propylene glycol, about 15 parts of polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

3. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

4. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of propylene glycol, and about 4 parts of water.

5. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

6. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 15 parts of propylene glycol, about 15 parts of polyethylene glycol having an average molecular weight of 300, and about 4 parts of water.

7. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and a chemotherapeutic agent.

8. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at room temperatures, about 4

parts of water, and about 0.1 part of an antibacterially active nitrofuran.

9. A pliant, non-adherent film adapted for use as a surgical dressing and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and about 0.1 part of 5-nitro-2-furaldehyde semicarbazone.

10. A surgical dressing comprising a pliant, non-adherent film containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures and about 4 parts of water, and having a reinforcing fabric embedded in one of its surfaces.

11. A surgical dressing comprising a pliant, non-adherent film containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 15 parts of propylene glycol, about 15 parts of polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures and about 4 parts of water, and having a reinforcing fabric embedded in one of its surfaces.

12. A surgical dressing comprising a pliant, non-adherent film containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures and about 4 parts water, and having a reinforcing fabric embedded in one of its surfaces.

13. A surgical dressing comprising a pliant, non-adherent film containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 15 parts of propylene glycol, about 15 parts of polyethylene glycol whose average molecular weight is about 300 and about 4 parts of water, and having a reinforcing fabric embedded in one of its surfaces.

14. A surgical dressing comprising a pliant, non-adherent film having a reinforcing fabric embedded in one of its surfaces and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and a chemotherapeutic agent.

15. A surgical dressing comprising a pliant, non-adherent film having a reinforcing fabric embedded in one of its surfaces and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and about 0.1 part of an antibacterially active nitrofuran.

16. A surgical dressing comprising a pliant, non-adherent film having a reinforcing fabric embedded in one of its surfaces and containing about 3 parts of polyvinyl alcohol of a grade which is at least 76% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and about 0.1 part of 5-nitro-2-furaldehyde semicarbazone.

17. A surgical dressing comprising a pliant, non-adherent film formed to fit the surface of a part of the human body and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

18. A surgical dressing comprising a pliant, non-adherent film formed in the shape of a glove to fit over the surface of a human hand and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, and about 4 parts of water.

19. A surgical dressing comprising a pliant, non-adherent film formed to fit over the surface of a part of the human body and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 30 parts of a plasticizer therefor comprised of a mixture of propylene glycol and polyethylene glycol having an average molecular weight between about 200 and 400 which is liquid at normal room temperatures, about 4 parts of water, and a chemotherapeutic agent.

20. A surgical dressing comprising a pliant, non-adherent film formed to fit over the surface of a part of the human body and containing about 3 parts of polyvinyl alcohol of a grade which is at least 98.5% hydrolyzed, about 15 parts of propylene glycol, about 15 parts of polyethylene glycol whose molecular weight is about 300, about 4 parts of water, and about 0.1 part of 5-nitro-2-furaldehyde semicarbazone.

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