

1

3,426,754

BREATHABLE MEDICAL DRESSING

Harvey S. Bierenbaum, Plainfield, Robert B. Isaacson, Rahway, and Peter R. Lantos, Plainfield, N.J., assignors to Celanese Corporation, New York, N.Y., a corporation of Delaware

No Drawing. Filed Sept. 14, 1966, Ser. No. 579,219
U.S. Cl. 128-156 13 Claims
Int. Cl. A61I 15/06; A61F 13/02; C09J 7/00

This invention relates to a new and useful type of breathable, porous, pressure-sensitive adhesive dressing and to the novel process of manufacturing same. In one embodiment, this invention relates to adhesive medical dressings of the type comprising a backing which is porous, which latter term must be regarded herein as extending from the highly porous to the microporous, and coated on one side with a spread of pressure-sensitive adhesive sufficient upon application to give adequate adhesion to the skin but leaving sufficient areas to permit sufficient aeration so as to constitute a wholly porous dressing. In another embodiment, this invention relates to improvements in bandages of the type having a protective covering or absorbent surgical compress secured to an adhesive surfaced backing strip which have the inherent characteristics of exclusion of liquids as well as other infectants and undesirable substances from the bandaged area while permitting the passage of air to that area.

Commercially available bandages are generally constructed of a sheet or strip of fabric or plastic which is provided on one side with an adhesive surface. The bandages may be precut to a desired configuration and may be provided with a surgical compress on that side to which said adhesive surface is affixed. In some instances, e.g. when the bandage is not rolled and is precut, facing strips of paper or other suitable material are temporarily secured to the adhesive strip in order to prevent adhesion of the bandage to its wrapper and to assist in preventing contamination.

Because it is widely recognized that a wound or injury heals most rapidly and satisfactorily when air is permitted to contact the injury continuously during the healing period, when a plastic backing strip is employed it has been customary to provide apertures or vent holes in same. The presence of such vents permits air to come in contact with the injury. Unfortunately, providing such apertures in the bandage in large measure defeats the basic purpose of the bandage since external infectants of various types gain ready access to the injury through them. The result is either a retardation of the healing processes or, where more virulent infectants or irritants are admitted, serious infection and increased incapacity of the injured area.

The problem is especially accentuated when the injury is on the hand or fingers since the hands are necessarily frequently immersed in water or other liquids. Obviously, when this is done the compress immediately absorbs liquid and the wound becomes wet and soft. In combination with a liquid soap pad, bacteria or irritants become and continue to be a hazard to the culmination of the healing process. For these reasons it may be preferable to construct a bandage having no vents or apertures. Infection of the injury is inhibited by constructing the bandage in this manner since the injury is protected against all outside contaminants including liquids. Healing is not, however, as rapid as it would be if the injury were exposed to air.

It is therefore a principal object of the present invention to provide a bandage which is capable of excluding liquids and other outside contaminants from an injured

2

area while admitting air to such area, thus protecting the injury and accelerating its healing. Further objects would be apparent from the consideration of the following disclosure.

The present invention provides a dressing comprised of a backing characterized by an open-celled structure, said backing preferably carrying a continuous but microporous pressure-sensitive adhesive coating. This adhesive is preferably a rubbery-based adhesive which is water-insoluble and viscoelastic, and the coating is aggressively tacky in its normal dry state. This adhesive coating is firmly anchored to provide a unitary integrated structure that will not be delaminated or split when the tape is unwound or removed.

An outstanding feature is that a novel dressing of the present invention is relatively non-irritating to the skin of most persons and does not cause maceration of the skin even after prolonged adhesive contact therewith. "Maceration" is a condition of the skin induced by prolonged contact with an adhesive dressing whereby the skin becomes soft, wrinkled and white due to the inability of the skin to breathe and to eliminate perspiration, and also due to its being shielded from air and light.

This outstanding feature is directly attributable to the type of film material employed as the backing for the dressings of the present invention. Such film comprises an entirely new type of porous material which, unlike the films of the prior art, possess an open-celled structure and is characterized by apparent densities lower than the polymer materials from which they are formed, usually no greater than 90%, preferably about 50 to 75% of the densities of the corresponding polymer materials. The sizes of the passageways to the voids or pore spaces of the open-celled structure accessible to the outside of the film are generally under 5000 angstrom units, e.g. 100 to 5000 angstrom units, as porosimetrically determined by mercury penetration, which measurement also determines the volume of such void or pore space. The final crystallinity of these films is at least 40%, preferably at least 50%, and more preferably 50 to 60%.

As used herein, the term "apparent density" signifies the weight per unit of "gross volume" of the film, where "gross volume" is determined by the amount of mercury infused into the film by high pressure. See R. G. Quynn et al. in Journal of Applied Polymer Science, vol. 2, No. 5, pages 166-173 (1959).

As used herein, the term "open-celled structure" signifies that the major portion of the void or pore space of the structure within the geometric confines of the film is accessible to the outside planar surfaces of the film.

The preferred backing for the dressings of this invention are films formed from precursor films of a relatively crystalline film-forming polymer having an elastic recovery at zero recovery time (hereinafter defined) at 25° C. and 65% relative humidity, of at least about 50% when subjected to a standard strain (extension) of 50%, and preferably an elastic recovery at zero recovery time of at least about 80% when subjected to a strain of 50%. The precursor films, as well as the preparation thereof, are further defined in copending application Ser. No. 572,601, filed Aug. 15, 1966.

It should be noted that although a standard strain of 50% is used to identify the elastic properties of the precursor films of this invention, such strain is merely exemplary. Such precursor films will, of course, generally have elastic recoveries even higher at strains less than 50% than they do at 50% strain, and such films also have relatively high elastic recoveries at strains substantially higher than 50%, e.g., from strains of say 100%.

The precursor film utilized must be differentiated from film formed from classical elastomers. With such classical

elastomers the stress-strain behavior, and particularly the stress-temperature relationship, is governed by an entropy-mechanism of deformation (rubber elasticity). The positive temperature coefficient of the retractive force, i.e., decreasing stress with decreasing temperature and complete loss of elastic properties below the glass transition temperature are particular consequences of entropy-elasticity. The elasticity of the precursor films of this invention, on the other hand, is of a different nature. In qualitative thermodynamic experiments with these precursors, increasing stress with decreasing temperature (negative temperature coefficient) may be interpreted to mean that the elasticity of said materials was not governed by entropy effects but depended on an energy term. More significantly, it was found that the precursor films of this invention retained their "stretch" properties at temperatures where entropy-elasticity could no longer be operative. Thus, it may be concluded that the "stretch" mechanism of the precursor films is based on energy-elasticity and may be referred to "non-classical" elastomers.

The above characteristics necessary to the precursor films can be accomplished by employing a critical combination of process variables and process steps. Broadly the necessary process steps comprise the forming, i.e. extrusion of the films under critical conditions followed by an annealing step to impart the desired degree of elasticity. The necessary process conditions comprise: (1) a rapid rate of drawdown, (2) a high drawdown ratio and, (3) a low melt temperature, i.e., a melt temperature substantially closer to the melt temperature of the film-forming polymer than in conventional extrusion processes.

The rapid rate of drawdown may be accomplished, for example, in slit die extrusion by providing the take-up roll or spool for the extruded film at a distance not more than two inches, and preferably, not more than one inch, from the extrusion slit or orifice. At the same time said takeup roll must be operated at a high rate, e.g., a speed of at least 25 feet/min. of the film, measured at said roll since the takeup rate of the film actually varies at the extrusion slit (where the film is relatively thick) and at the takeup roll (where the film is comparatively thinner).

The drawdown ratios suitably employed to prepare the precursors range as high as 1000:1 and preferably range from about 75:1 to about 125:1.

The melt temperature for extrusion of the precursors is in general no higher than 100° C. above the melting point of the polymer and most suitably in the range of 10 to 40° C. above such melting point, while the drawdown ratio of extrusion, i.e., ratio of linear velocity of the takeup roll to the linear velocity of extrusion is at least 20:1. The annealing step is generally carried out at a temperature in the range of about 5 to 100° C. below the melting point of the polymer for a period of at least 1 second.

The first of two essential steps to be used to prepare suitable backing film is a drawing step wherein the film is drawn or stretched. This can be done continuously in connection with an extrusion unit or the film may be drawn in a separate step. Regardless of which procedure is followed, the extruded film must be drawn to accomplish the objects of the invention. By "extruded" film is meant film as it first solidifies on emergence from the extruder. The extruded film is drawn to impart the open-celled structure and to reduce the apparent density of same. The precise degree of drawing is important to this invention in that an optimization of useful properties takes place at intermediate extensions rather than at the highest amounts of stretch.

In order to obtain the characteristics mentioned hereinbefore, the extruded films may be drawn or extended from about 10% of their original length up to about 300% of their original length or higher. While an extension of greater than 300% can be employed it ordinarily would not be employed since improvement in the open-celled structure is only slight in most instances and, in some

instances, may actually be detrimental to the structure. To obtain optimum levels of the characteristics mentioned hereinbefore, the extruded films must not be drawn or extended to an amount greater than 150% of their original length. In order to attain maximization of the desired utility of the immersion, e.g., maximum gas permeability, dye receptivity, etc., optimum pore size and the like, it is especially preferred to extend the film from 30% to 120% of their original lengths and it is most preferred to extend the film about 50 to 100% of their original lengths.

The precursor film is preferably "cold drawn" to impart the desired voidy structure. In this operation the film is drawn at the above draw ratios at ambient or near-ambient temperatures. The drawing per se may be performed in any convenient manner using known techniques where a film is positively forwarded by one moving means to a second moving means operating at a higher speed. The temperature of the film per se being drawn is referred to herein as the draw temperature.

It is also contemplated to draw the film at sub-ambient temperatures, as well as at temperatures above ambient. However, the upper limit of the draw temperature range has been found to be critical and it is essential that this limit not be exceeded. For example, it has been discovered that substantial reduction in the apparent density of polypropylene film can be effected up to a temperature of about 200° F. (93.3° C.) but when this temperature is exceeded there is a marked decrease in the reduction of the apparent density of the film. Surprisingly, in this instance essentially no reduction can be accomplished when the upper limit of the drawing operation is exceeded by about 20° F. (11.1° C.) Accordingly, the polypropylene films used herein are preferably not drawn at a temperature in excess of the 220° F. upper limit, the acetal films at a temperature not in excess of 255° F. and the polyethylene film not in excess of 220° F.

When the film is drawn at temperatures above ambient, said film may be heated by any conventional means. Preferably the film is heated by heated, moving rolls. However, the film may also be heated by passage over a heated plate, through a heated liquid, a heated gas, or the like.

The second essential step in the process of preparing backing film is the step of heat setting or annealing the film, after the drawing thereof, while said film is in the tensioned state. It has been found that heating the drawn film in a tensioned state at a temperature below the melting point of the polymer has a remarkable influence on the dimensional stability of the open-celled, low density characteristics of same. Accordingly, the drawn film is stabilized against excessive shrinkage, etc. by heating at a temperature which may be somewhat higher than the drawing temperature and while being held under a tension such that the film is not free to shrink or can shrink to only a controlled extent, e.g., not greater than 15% of the initial length. In order to insure maximum relaxation of the strains introduced into the films during the earlier processing thereof and thus impart the desired stability, the heat treatment is preferably carried out at a temperature within the range of from about 100° C. to about 160° C. for polypropylene, 100 to 160° C. for acetal polymers, 100 to 135° C. for polyethylene, etc. The period of heat treatment should be no less than about 0.1 second and may be within the range of about 0.5 second to about 30 minutes, preferably about 2 seconds to 15 minutes. The drawing operation and the heat treatment should be carried out sequentially, e.g., by first stretching the film and then heat setting in a conventional manner. As may be surmised from the foregoing discussion, the apparent density of the resulting heat treated low density film is significantly below that of the precursor film.

The resultant film suitable for use herein, in a tensionless state, has an apparent density lower than the density of the polymeric material from which it is formed,

usually no greater than 95%, preferably about 50 to 75% of the densities of the corresponding polymer material. The sizes of the passageways to the void or pore spaces of the open-celled film structure accessible to the outside planar surfaces of the film are under 5000 angstrom units, e.g., 150 to 5000 angstrom units, as poro-

simetrically determined by mercury penetration, which measurement also determines the volume of such void or pore space. The final crystallinity of these films is preferably at least 30%, more preferably at least 40% and more suitably at least 50%, e.g., 50 to 100%.

As stated, the elastic precursor films employed in this invention are composed of a polymer of a type capable of developing a significant degree of crystallinity, as contrasted with more conventional or "classical" elastic materials such as a rubber which are substantially amorphous in the unstretched or tensionless state.

A significant group of polymers which may be utilized are the olefin polymers, e.g., polypropylene, poly-3-methyl butene-1, poly-4-methyl pentene-1, polyethylene as well as copolymers of propylene, 3-methyl butene-1, 4-methyl pentene-1, or ethylene with each other or with minor amounts of other olefins, e.g., copolymers of propylene and ethylene, copolymers of a major amount of 3-methyl butene-1 and a minor amount of a straight chain n-alkene such as n-octene-1, n-hexene-1, n-hexadecene-1, n-octadecene-1, or other relatively long chain alkenes, as well as copolymers of 3-methyl pentene-1 and any of the same n-alkenes mentioned previously in connection with 3-methyl butene-1. These polymers in the form of films generally have a percent crystallinity of at least 50%, e.g., 50 to 60%.

Another group of polymers which may be used are high molecular weight acetal polymers i.e. both homopolymers and copolymers. While acetal (or oxymethylene) homopolymers are contemplated, the preferred oxymethylene polymer is a "random" oxymethylene copolymer, i.e., one which contains recurring oxymethylene, i.e., $-\text{CH}_2-\text{O}-$, units interspersed with $-\text{OR}-$ groups in the main polymer chain where R is a divalent radical containing at least two carbon atoms directly linked to each other and positioned in the chain between the two valences, with any substituents on said R radical being inert, that is, those which do not include interfering functional groups and which will not induce undesirable reactions, and wherein a major amount of the $-\text{OR}-$ units exist as single units attached to oxymethylene groups on each side. Examples of preferred polymers include copolymers of trioxane and cyclic ethers containing at least two adjacent carbon atoms such as the copolymers disclosed in United States Patent No. 3,027,352 of Walling et al. These polymers in film form also have a crystallinity of at least 50%, e.g., 50 to 60%.

Other relatively crystalline polymers which are suitable are polymethylene sulfide, polyethylene sulfide, polyphenylene oxide, polyamides such as polyhexamethylene adipamide (nylon 66) and polycaprolactam (nylon 6) and polyesters such as polyethylene terephthalate.

The types of apparatus suitable for forming the precursor film products of this invention are well known in the art. For example, a film extruder equipped with a shallow channel metering screw and coat hanger die is satisfactory. The resin is introduced into a hopper of the extruder which contains a screw and a jacket fitted with heating elements. The resin is melted and transferred by the screw in the die from which it is extruded through a slot in the form of a film from which it is drawn by a take-up roll. Obviously, more than one take-up roll in various combinations may be used.

Using this type of apparatus, film may be extruded at a drawdown ratio of about 20:1 to 1000:1, preferably 75:1 to 150:1. The die opening or slot width may be in the range, for example, of about 30 to 200 mils. Polypropylene may be extruded at a melt temperature of

about 180° to 240° C., preferably 195° C. to 225° C. while acetal polymers, e.g., of the type disclosed in U.S. Patent No. 3,027,352, may be extruded at a melt temperature of about 185° C. to 235° C., preferably 195° to 215° C. Polyethylene may be extruded at a melt temperature of about 175 to 225° C.

The extrusion operation is necessarily carried out with rapid cooling and rapid drawdown in order to obtain maximum elasticity. This may be accomplished by having the take-up roll relatively close to the extrusion slot, e.g., within two inches and, preferably, within one inch, and rotating as fast as possible without breakage. An "air knife" may be employed within one inch of the slot. The take-up roll may be rotated, for example, at a speed of 20-1000 ft./min., preferably 50 to 500 ft./min.

An alternative method of forming the precursor films of this invention is the blown film extrusion method wherein a hopper and an extruder are employed which are substantially the same as in the slot extruder described above. From the extruder, the melt enters a die from which said melt is extruded through a round slot to form a tubular film having an initial diameter D_1 . Air enters the system through an inlet and is distributed by means of air ring or similar means through an opening into the interior of said tubular film and has the effect of blowing up the diameter of the tubular film to a diameter D_2 . A second source of air is also provided and impinging means direct this air about the extruded tubular film so as to quickly and effectively cool same. After a short distance during which the film is allowed to completely cool and harden, it is wound up on a take-up roll.

Using the blown film method, the drawdown ratio is preferably 20:1 to 200:1, the slot opening 20 to 200 mils, the D_2/D_1 ratio 0.5 to 6.0 and the takeup speed 30 to 700 ft./min. The melt temperature may be within the ranges given previously for straight slot extrusion.

As stated previously, the extruded precursor film may be initially annealed in order to develop the desired range of elasticity. One method of carrying out the annealing step is through the use of hot rolls wherein the annealing time is generally in the range of about 5 to 90 seconds or longer. Another method is placing the film in the tensionless state in an oven at the desired temperature in which case the residence time is preferably in the range of about 30 seconds to 1 hour.

In accordance with the invention, the extruded, and, if desired, annealed, film passes over a roll and into suitable stretching means. The drawn film then passes into a heater and over a roll to a windup means. Means may also be provided so that the film passing through the heater is held against shrinkage or shrinks to a controlled extent. The rate of feed of the film to the heaters and the heating times are correlated so that at the selected drawing and stabilizing temperature, the desired objectives are accomplished.

The heater utilized, as mentioned, may be heated in any suitable manner, for example, by a heated plate, heated liquid, a heated gas, etc. These, obviously, may be substituted by any equivalent heating medium.

By means of the foregoing process, polypropylene film may be obtained having, at 25° C. and 65% relative humidity, an elastic recovery from 50% extension of 50 to 90%, a tensile strength of 10,000 to 35,000 p.s.i., a breaking elongation of 200 to 350%, a modulus of 100,000 to 500,000 p.s.i. (all the foregoing in the machine direction). In addition, such polypropylene film generally has other properties within the following ranges: a haze of 20% to opaque, an O_2 transmittance of 100,000 to 150,000 and N_2 transmittance of 100,000 to 150,000 and a CO_2 transmittance of 15,000-30,000, water vapor transmittance of as high as 400, generally 100 to 350, the units of transmittance of the last four instances being given in cc./24 hrs./m.², atm. Other properties are void volume .565 to .075 cm.³/gm., density .60 to .85 gm./cm.³, and a pore size

of 150 to 5000 angstroms, the values of the last three properties being determined by mercury porosimetry.

Films prepared in accordance with this process of oxy-methylene or acetal copolymers (such as those disclosed in Patent No. 3,027,352) generally have properties in the machine direction within the following ranges at 25° C. and 65% relative humidity: elastic recovery from 50 to 90%, tensile strength of 8,000 to 50,000 p.s.i., breaking elongation of 25 to 150%, modulus of 100,000 to 450,000 p.s.i. In addition, such film generally has a haze of 20% to opaque, a density of .95 to 1.3 g./cm.³, a void volume of .343 to .061 and a pore size of 150 to 5000 angstroms, the values of the last three properties being determined by mercury porosimetry. The foregoing properties are merely illustrative of typical film profiles and do not therefore, limit the scope of the invention.

The present invention contemplates the use of any highly gas- and moisture permeable adhesive coating for the film herein. Preferably, the process of forming the continuous adhesive coating is of such a nature that, during the drying of the coating, innumerable, pore-like apertures spontaneously develop therein and these pores result in a viscoelastic porous adhesive membrane covering the porous backing. These pores are so minute that they are not visible to the human eye upon casual inspection of the film—the adhesive coating thus being of a visibly continuous nature. They are, however, of sufficient size and closeness together to permit of ample transpiration of skin moisture and wound vapors, and to permit of absorption of liquid material therethrough into the porous film backing. The effect is essentially uniform over the entire contacted body area; as distinguished from the effects produced by tapes which have relatively large holes or apertures therein, or which have been perforated by needles, or which have discontinuous spaced-apart stripes or spots of ordinary impermeable adhesive on a porous backing, to obtain a so-called "breathable" tape, as suggested in the prior art. The continuous uniform microporous reticular nature of the present tape is a decided advantage.

If desired, use can be made of rubber-base pressure-sensitive adhesive coating compositions that are free from extraneous or undesirable non-volatile components or ingredients, and from liquid plasticizers, thereby avoiding the presence in the dried adhesive coating of substances which impair adhesion or cohesion or which may cause or promote skin irritation. For instance, use can be made of pure viscoelastic polymers which are inherently aggressively tacky and highly cohesive and which are relatively non-irritating to the human skin, such as the pressure-sensitive acrylate polymers. This latter adhesive is not only water-insoluble but it is hydrophobic as indicated by the fact that drops of water deposited on the surface do not flow out and wet the surface. The microporosity of the adhesive coating obviates the need of including any moisture-absorptive material in the adhesive composition.

In a preferred embodiment for the fabrication of the dressings of this invention, the viscoelastic pressure-sensitive adhesive is applied to the porous backing film in such a way as to provide thereon a continuous soft sticky viscid coating containing a volatile vehicle which is in small enough proportion to avoid wicking or penetration of the adhesive through the body of the porous film backing, when it is promptly dried after application. Further drying of the semi-dry adhesive coating results in progressive loss of the residual volatile vehicle and a shrinkage of the coating. These capillary and shrinkage effects produce a strain in each tiny portion of the viscoelastic adhesive film which bridges a backing passageway, and in yielding to this strain one or more minute openings (pores) are autogenously formed therein. In this way the entire adhesive coating, during drying, autogenously develops a vast number of closely spaced pores per square inch, producing a microporous reticulated structure in

an adhesive film that remains visibly continuous and provides a unitary microporous film-adhesive web.

The necessary degree of adherency of the tape is not prevented by the presence of these pores. The viscoelastic property of the adhesive prevents the pores from closing up even during prolonged pressing of the adhesive in a roll of tape and even when the tape is used for strapping.

The use of the thin and pliant nonwoven film backing which constitutes a necessary element of this invention and carrying a thin, smooth adhesive coating results in a highly conformable tape which is more comfortable to the patient and makes for less bulky dressings. Use of an adhesive which is aggressively tacky but is more rubbery and firmer than conventional surgical tape adhesive (which are loaded with softeners and pigments) is desirable, and is provided by the previously mentioned acrylate polymer adhesive. Such tape can be removed more readily and comfortably from the skin after prolonged contact and yet is readily applied and immediately adheres to the skin with adequate adhesion when pressed into place. Furthermore, the elasticity of the film backing utilized herein can be maintained, e.g., at 50% extension a recovery of 80% can be obtained, so that the tape or dressing will retain and hold the skin in its initial position and that strappings will not develop slackness, which is not true of conventional cloth-backed surgical tapes.

Application of the adhesive to the porous film backing may be accomplished by a variety of methods. One convenient way to carry out this process is first to prepare in the usual way a solution of the adhesive in sufficient solvent (volatile vehicle) to provide a coatable viscosity. This adhesive solution is then coated on a liner web having a dense, nonporous, shiny-smooth surface of an "anti-stick" nature that will permit of ready separation from the adhesive coating in its subsequent semi-dried and fully-dried states. This adhesive coating is partially dried by passing the web into a hot air drying oven or over a heated drum, and is brought into laminar bonding contact with a superimposed web of the porous backing fabric. The resulting "sandwich" web is then promptly further heated to eliminate the residual solvent from the adhesive coating, during which interval the adhesive coating acquires the desired porous state (which is retained in the fully dried product) and upon completion of the drying operation to fully remove the solvent, it is wound up in a jumbo roll. Drying of the applied adhesive coating layer is conducted with sufficient promptness to prevent the adhesive from soaking or striking through the body of the porous film backing. The evaporating solvent is free to escape through the porous backing web. Drying of the adhesive coating while at all stages in contact with the impermeable, smooth, shiny surface of the liner, results in the dried adhesive coating having a smooth dense outer surface characteristic. During the porosity-inducing phase of the drying, the adhesive contact to the liner is disrupted at the points where the pores are formed. This is permitted by the anti-stick surface which allows the adhesive to pull away from it where the pores develop, leaving the surrounding adhesive surfaces in continued contact with the liner surface.

This dried composite sheeting is subsequently unwound from the jumbo roll, the liner is stripped off, and the adhesive-coated web is slit and wound upon itself in tape rolls of desired size. If desired, the liner can be left in place during slitting and winding to facilitate subsequent handling of the tape; as in withdrawing tape from a large roll and (after removal of the liner) fabricating first aid bandage or corn plaster strips which carry a medicated or nonmedicated pad adhering to the adhesive surface. The liner-carrying tape can also be cut into strips of desired length to be packaged and sold as wound-closure tapes, the liner covering the adhesive surface until it is removed just prior to use of the tape.

Instead of using a liner web in the manufacture of the tape (as just described), the adhesive solution can be

coated on a moving endless casting belt or drum having a polished antistick surface, such as are known in the film-casting art. After preliminary partial drying of the adhesive coating, the tape backing web is laid on the adhesive layer and further drying is employed to produce the porous adhesive web product. The dry product is then stripped from the belt or drum and is either directly slit and wound into tape rolls or is combined with a smooth-surfaced anti-stick liner web and handled as previously described. It will be evident that these procedures also result in a tape having a smooth adhesive surface.

Another alternative is to pull the porous backing web around on a rotating heated drum serving as a support and a heating means. The adhesive solution is coated on the web as it rests on the drum, and a high enough drum temperature is employed to quickly dry the coating before it has a chance to wick through the body of the web. The adhesive coating develops the desired porous structure while the web is still on the drum. The dried product is then handled as before. In this last alternative, the adhesive coating is dried with its external surface exposed to the atmosphere and does not have the degree of smoothness that is obtainable when the adhesive is dried in contact with an impermeable shiny-smooth supporting surface as in the earlier-described procedures. However, greater smoothness can be imparted by applying a shiny-smooth anti-stick liner to the adhesive side of the web and winding in a roll which is then stored before unwinding and slitting.

The transpiration porosity of the tape is such as to provide a moisture vapor transmission rate that exceeds the perspiration emission rate of the human skin under ordinary conditions. The permeable or porous adhesive coating is hydrophobic but is (in common with other such adhesives) capable of softening and swelling upon prolonged contact with liquid perspiration. However, due to transpiration of perspiration through the pores, there is much less tendency for the adhesive to soften or lose tackiness upon prolonged contact with perspiring skin, than is the case where the ordinary non-porous type of adhesive is used. Perspiration from the underlying skin can pass through the adhesive coating either as vapor, or as liquid which is absorbed by the porous capillary structure of the backing and thence evaporated, so that in any case the skin is maintained in a dry state under ordinary conditions. These features result in retention of the tape and the skin in the initial position. This is particularly important in the case of wound closure tapes, i.e., tape strips used for closing cuts or wounds and keeping them closed during healing, thereby in many cases avoiding the need of suturing.

The present invention also contemplates a variety of surgical dressings which may be prepared in many forms and for many different uses, and the basic elements that might be considered as constituting a surgical dressing include a pad or facing which may be applied to a wound or surface which is being dressed and a wrapping or cover which functions to hold the facing in position. Conventionally, the facing is usually in the form of gauze or similar soft relatively absorbent material. Thus, the term "dressings" as contemplated in the present invention and as defined above and in dictionaries includes sanitary napkins, diapers and other diverse medicators and receptors, all of which normally have an absorbent pad which is applied to the surface which is being dressed and a backing or wrapping which functions to hold the absorbent material in position.

It has also been discovered that artificial sponge materials of regenerated cellulose type, as conventionally produced and, commonly available, have properties of texture, porosity, resilience and absorptivity eminently suiting them for use as facing or contact material against flesh as in the facing of a dressing.

In a special embodiment of the present invention, various antiseptic, bactericidal, or treatment agents may be

used in combination with the dressing of the present invention. Such agents may be employed by application in conjunction with the above-mentioned pad or facing or in conjunction with the dressing per se, i.e. encapsulated or entrapped in pores of the film. This latter embodiment in which the agents are contained in the film-dressing is of special importance. Thus, it is contemplated that liquid medicating agents may be introduced into the films as well as powders or like solids which react with body fluids or water and which serve as slow acting disinfectants and enhance the use of the dressing as a poultice.

Various methods may be employed to incorporate the liquid or dry medicating agents into the film. (In the instance of dry agents, such agents are generally solvated in a suitable solvent or, if sufficiently minute in particle size, suspended in a suitable fluid vehicle.) One such method comprises providing a fluid reservoir of medicating agent through which the hereinbefore described precursor film is passed. Means are provided for stretching the submerged portion of the precursor film so as to form the desired voids or pore spaces which are then substantially filled with the medicating agent. The stretched film is then released so as to encapsulate or entrap said medicating agent.

Another method comprises drawing and heat setting the precursor film in accordance with the technique hereinbefore described to produce a film containing voids or pore spaces. Such film is then immersed in a liquid reservoir of medicating agent and is then heat treated in any untensioned state at a temperature at least slightly higher than the heat setting temperature in order to reduce or dissipate the pores and encapsulate the medicating agent therein.

It is to be understood that the films may be treated as above in either their entirety or selected portions or areas of said films may be treated. Thus innumerable configurations of adhesive-medicated film may be prepared employing combinations of encapsulation and adhesive application techniques. An especially advantageous embodiment comprises a strip of the porous film of the present invention, the mid area of which contains an encapsulated antiseptic, bactericidal or treatment agent. The remaining portions of the film are coated on one side with a pressure-sensitive adhesive thus providing exposed areas of adhesive on opposite sides of the medicating agent-containing area. In applying this adhesive bandage, tensile force is applied in opposing directions so as to stretch the mid portion of the bandage thereby releasing the medicating agent.

The invention is further illustrated by the following examples.

Example I

This example illustrates the preparation of a film suitable for use in the invention. The film-forming polymer of this example was a copolymer having a melt index of 2.5, of trioxane and 2 weight percent based on the weight of the polymer of ethylene oxide of the type described in U.S. Patent No. 3,027,352, after-treated to remove unstable groups as described in Patent No. 3,219,623, and suitably stabilized.

The above-described polymer was melt extruded at 375° C. through an 8" slit of the coat hanger type at a shear rate of approximately 46 reciprocal seconds using a 1" extruder with a shallow channel metering screw. The length to diameter ratio of the extruder barrel was 24:1. The extrudate was drawn down very rapidly to a drawdown ratio of 270:1, contacted with a rotating casting roll maintained at 289° F. and about 1/4" from the lip of the die. The film produced in this manner was wound up and found to have the following properties:

Thickness	-----inches	.0005
Recovery from 50% strain	-----percent	46

The polymer was then oven annealed in the tensionless state at 145° C. for 16 hours. At the end of the annealing period it was removed from the oven, allowed to cool and found to have the following properties:

Thickness	inches	.0005	5
Recovery from 50% elongation at 26° C.	percent	92	
Density as determined by mercury porosimetry	g./cm. ³	1.40	10

The film was extended at room temperature to 189% of its original length, held in the extended state by metal clamps and heat set in an oven at 150° C. for two minutes. At the end of this period it was removed from the oven, allowed to cool and found to have the following properties:

Void volume is determined by mercury porosimetry	cm. ³ /gm	.18	
Density as determined by mercury porosimetry	gm./cm. ³	1.12	20
Pore size as determined by mercury porosimetry	A	100-900	

Example II

This example illustrates the preparation of another film suitable for use herein. In this example crystalline polypropylene of melt index 4.0 and density .905 g./cc. was melt extruded at 380° F. through an 8" slit die of the coat hanger type using a 1¾" extruder with a shallow channel metering screw. The length to diameter ratio of the extruder barrel was 24:1. The extrudate was drawn down very rapidly to a drawdown ratio of 90:1, contacted with a rotating casting roll maintained at 184° F. and ¼" from the lip of the die. The film produced in this fashion was found to have the following properties:

Thickness	inches	.001	
Elastic recovery from 50% strain	percent	49	

The resulting film was divided into two pieces which then were oven annealed at 130° C. for 15 minutes. At the end of this period they were removed from the oven and allowed to cool. Piece No. 1 was stretched 190% at room temperature and heat set in the extended state for 15 minutes at 130° C. Piece No. 2 was unchanged after the first annealing step. Mercury Porosimetry (infusion) analysis of both samples gave the following results:

	Sample No. 1	Sample No. 2
Penetration volume (cm. ³ /gm.)15	.01
Density (gm./cm. ³)79	.89
Pore size (A.)	100-1,100

The values of "recovery" given above are elastic recovery determined as follows at 25° C. and 65% relative humidity:

A sample 15 mm. in width was placed in an Instron tensile property testing machine with the jaw separation being 2" apart. The sample was extended at the rate of 1"/min. until 50% extension was reached. The sample was held at that extension for 1 minute and then relaxed at the same rate as extended. A reading was recorded as soon as a no load condition was indicated by the Instron. The elastic recovery is then calculated as follows:

Elastic Recovery =

$$\frac{\left(\begin{array}{c} \text{Total Length} \\ \text{When Extended} \end{array} \right) - \left(\begin{array}{c} \text{Final Distance} \\ \text{Between Jaws} \end{array} \right)}{\text{Length Added When Extended}} \times 100$$

The other properties mentioned were determined with standard ASTM methods as follows:

Tensile strength—ASTM #D882—Method A Sample width 15 mm.	
Breaking elongation—ASTM #D882—Method A Sample width 15 mm.	

Modulus—ASTM #D882—Method A Sample width 1 inch.

Moisture vapor transmittance—ASTM 9663T—Method B, Procedure B

O₂, N₂, CO₂ transmittance—ASTM #D1434-63, Dow Cell Method, except that because of exceedingly high gas permeability, two pieces of film were laminated together with Interchemical Coating #NB483C which was less than .0001 inch in thickness.

Density—As determined by Mercury Penetration. See Textile Research Journal, vol. 33, pps. 21 et. seq. (1963), by R. G. Quynn.

Haze—ASTM #D1003—Procedure A as per FIGURE 2.

The values of percent crystallinity given above are determined using the procedure described in an article by R. G. Quynn et al. in Journal of Applied Polymer Science, vol. 2, No. 5, pages 166-173 (1959).

Example III

This example illustrates the preparation of an adhesive dressing utilizing the porous film of Example I and constitutes a preferred embodiment of the invention.

The pressure-sensitive adhesive employed in this example is a pure rubbery copolymer of isooctyl acrylate and acrylic acid in a 94:6 ratio. A solvent dispersion thereof is coated on a heated drum from which the dried polymer is removed and redispersed in a mixed solvent of heptane and isopropyl alcohol (70:30) to provide a 22% solution of coatable viscosity. This procedure eliminates volatile ingredients of the original polymer solution.

This adhesive solution is then coated on a moving liner having an insoluble, heat-resistant, shiny-smooth, anti-stick surface (such as a paper liner carrying a silicone resin release coating) in a wet coating weight adequate to provide a dry adhesive weight of about 50 pounds per thousand square yards. This wet adhesive coated web is promptly drawn into and through a hot air heating oven so arranged that after initial drying of the adhesive to a semi-dry state, the above-described backing web is layed down on the adhesive and becomes adhesively laminated thereto. An air temperature of 100-150° F. is preferably employed. Too high a temperature will cause a spongy adhesive coating or make control difficult. The objective at this point is to dry partially the adhesive to a degree that will prevent wicking through the superimposed porous backing and yet retain enough solvent in the adhesive coating to develop the desired microporous structure after lamination. The degree of porosity that is developed is roughly inversely proportional to the heating interval in this stage. In this example, a prelamination drying interval of approximately ½ minute at 100° F. has been found satisfactory under the conditions employed. However, the optimum time for any given factory installation should be determined by trial-and-error, as it is dependent upon the oven arrangement and operating conditions. Adjustment can be made by varying the rate of travel of the web. Continuing through the drying oven, the laminated "sandwich" web is further heated to develop the microporous adhesive structure and then to fully eliminate residual solvent and thereby complete the drying. In this example, satisfactory results have been obtained by passing the laminated web through successive oven sections adapted to heat it at 100° F. for 10 minutes.

The resultant adhesive sheeting has a caliper thickness of 4 to 6 mils (100 to 150 microns). The thin adhesive coating (which extends into the fibrous backing) contributes only ½ mil about 15 microns) of the total thickness.

Example IV

This example illustrates a technique for encapsulating a medicating agent into a precursor film for subsequent use as a dressing or poultice.

A roll of polypropylene precursor film similar to that

prepared in Example II and having width of 12 inches was fed through a first set of drive rolls and under a pair of idler rollers immersed in a reservoir of a 3% (in alcohol) solution of merthiolate. The film was then fed through a second set of drive rollers which travelled at a peripheral speed twice that of the first set thus stretching the immersed film about 100%. The film was then accumulated on a wind up roll which was driven at a speed substantially that of the first set of drive rolls, thereby allowing the film to substantially return to its original length and encapsulate the merthiolate solution therein. The film was slit prior to wind up to various widths ranging from 1/2 inch to 2 inches.

It is to be understood that the speed of the rolls can be intermittently changed so as to effect encapsulation in predetermined areas, thus preparing a film to which an adhesive may be suitably applied.

It is to be understood that the foregoing detailed description is given merely by way of illustration and that many variations may be made therein without departing from the spirit of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A microporous breathable dressing comprising a film of a polymer: said film being characterized by an apparent density lower than the actual density of said polymer from which said film is prepared and by a microporous structure wherein the pore spaces of said structure accessible to the outside of said film range from about 100 to 5000 angstrom units, as porosimetrically determined by mercury penetration.

2. The article of claim 1 wherein at least a portion of one side of said film carries a pressure-sensitive adhesive coating.

3. The article of claim 2 wherein said adhesive coating is a microporous coating of a water insoluble and viscoelastic adhesive.

4. The article of claim 1 wherein a pad of absorbent material is positioned on at least a portion of one side of said dressing.

5. The article of claim 1 wherein a mid portion of one side of said dressing has a pad of absorbent material positioned thereon and the remaining portion of the same side of said dressing carries a pressure-sensitive adhesive coating therein.

6. The article of claim 1 wherein at least a portion of said film has a medicating agent encapsulated therein.

7. The article of claim 6 wherein that portion of said film which contains no medicating agent encapsulated therein carries a pressure-sensitive adhesive coating on one side thereof.

8. The article of claim 1 wherein the polymer has a crystallinity of at least 40%.

9. The article of claim 1 wherein the polymer is polypropylene.

10. The article of claim 1 wherein the polymer is an oxymethylene polymer.

11. The film of claim 1 wherein the polymer is polyethylene.

12. The article of claim 4 in the form of a sanitary napkin.

13. The article of claim 4 in the form of a diaper.

References Cited

UNITED STATES PATENTS

2,838,045	6/1958	Ryznar	128—56
2,923,298	2/1960	Dockstader et al.	128—296
3,121,021	2/1964	Copeland	117—122

ADELE M. EAGER, *Primary Examiner.*

U.S. Cl. X.R.

128—260, 268; 117—122