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(54) Title: MEDICAL CONTACT ADHESIVE

(57) Abrégé/Abstract:
A medical pressure-sensitive adhesive based on polyacrylates is characterized in that it comprises the following components: a) a self-adhesive polyacrylate copolymer containing at least 3 mol-per cent of copolymerized acrylic or methacrylic acid b) a polymer containing basic amino groups c) a plasticizer.

A B S T R A C T

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MEDICAL CONTACT ADHESIVE

D E S C R I P T I O N

Materials with pressure-sensitive adhesive properties have been employed for a long time and for a very wide variety of uses in human medical care. Examples which may be mentioned are quick dressings, fixing plasters, self-adhesive electrodes, orthopaedic tapes and, in particular more recently, plasters containing an active substance.

Since these pressure-sensitive adhesives come into contact with human skin, an important requirement is that they must not have any primary skin irritation properties nor any allergenic potential. The allergenic potential is a specific problem of pressure-sensitive adhesives based on natural rubber or on comparable synthetic polymers. Since the latter are primarily nonadhesive, it is necessary to add so-called tackifiers which are usually derivatives of tree resins, i.e. rosin derivatives. These rosin derivatives are normally employed in the form of a mixture and, at least on repeated use, induce sometimes severe allergic reactions in a not inconsiderable number of people.

Modern pressure-sensitive adhesives based on synthetic polyacrylate polymers and silicones are self-adhesive merely on the basis of their molecular weight distribution and the monomers used, even without the addition of tackifiers, and have a very low allergenic potential. Such pressure-sensitive adhesives are termed hypoallergenic. Although it is possible to regard the problem of skin compatibility as having been solved with these pressure-sensitive adhesives, even they do not meet all of the requirements that are to be made of high-performance medical pressure-sensitive adhesives.

One problem is that medical pressure-sensitive adhesives are employed on the human skin, which is subject to marked changes in condition from one individual to the next. For instance, as a biological

tissue the skin alters its substrate properties in dependence on the particular living conditions and/or environmental conditions. A major problem here is the sweating of the skin under physical stress and/or under conditions of illness, and at high ambient temperatures. Nevertheless, a medical pressuresensitive adhesive must ensure secure adhesion to the skin even under these conditions. One possible way of achieving this is to make the pressure-sensitive adhesive as aggressive as possible in its adhesion. The corollary of this, however, is that the adhesive is then very soft, and it is virtually impossible to avoid the unwanted situation where residues of adhesive remain stuck to the skin.

An ideal pressure-sensitive adhesive, therefore, should possess a minimal degree of tackiness which changes into a more aggressive tackiness only under the action of moisture. In the case of polyacrylate adhesives, the tackiness is determined by the nature of the monomers used for the synthesis and, in particular, by its mean molecular weight and the molecular weight distribution. Here, low molecular weights lead to a soft and aggressive adhesive.

The object of the invention is to provide a pressuresensitive adhesive of adequate minimal adhesion which changes its molecular weight distribution under the action of moisture and, in doing so, passes into a state of more aggressive tackiness.

This object is achieved by means of the invention for a pressure-sensitive adhesive based on polyacrylates through a composition which is crosslinkable through metal chelates and has no skin-irritating and no allergenic effects. The composition comprises the following components:

a) a self-adhesive polyacrylate copolymer containing at least 3 mol-per cent of copolymerized acrylic or methacrylic acid

b) a polymer containing basic amino groups

c) a plasticizer.

Following removal of solvent, the medical pressure-sensitive adhesive comprises:

a) 75 - 94 % by weight of self-adhesive polyacrylate copolymer containing at least 3 mol-per cent of copolymerized acrylic or methacrylic acid,

b) 1 - 20 % by weight of polymer containing basic amino groups, and

c) 5 - 20 % by weight of plasticizer.

The polymer containing basic amino groups can be a polyacrylate or polymethacrylate copolymer and contain amino alcohol esters of acrylic or methacrylic acid incorporated by polymerization. The polymer containing basic amino groups can be dimethylaminoethyl methacrylate and neutral methacrylic esters.

The said adhesive is suitable for use in the preparation of quick dressings, fixing

plasters or self-adhesive electrodes and of plasters containing an active substance.
Within this adhesive there is an interaction between the acidic carboxyl groups of the polyacrylate polymer and the polymer containing basic groups. The adhesive is therefore in a state of crosslinking which results in an increase in molecular weight.

Crosslinking reactions play an important part with regard to polyacrylate adhesives. If the adhesive possesses hydroxyl or carboxyl groups, then it is possible by adding, say, metal chelates to crosslink the adhesive in the course of removing the solvents. In that case one speaks of autocrosslinking adhesives. The advantage of these adhesives is that solutions of adhesive are obtained which combine a high solids content with low viscosity. With these adhesives, the ultimate molecular weight distribution is established only after the solvents have been removed.

Whereas this type of crosslinking is irreversible, crosslinking through the interaction of basic and acidic functional groups remains fully reversible. Since, in this case, the crosslinking is brought about not by chemical bonding but merely by way of electrostatic forces, it can be weakened by - for example - water as a result of its high dielectric constant. In this case the adhesive behaves as if it is changing its molecular weight distribution. It becomes softer, begins to adhere more aggressively, and thus adapts to the particular requirements. This type of crosslinking can therefore be termed "dynamic crosslinking". Since the skin, depending on the prevailing circumstances, gives off a greater or lesser amount of moisture, this effect also occurs in the case of the adhesive of novel composition when applied to the skin.

In accordance with the invention, a plasticizer is mixed in with the pressure-sensitive adhesive in order to achieve a certain minimum or basic tackiness. The amount of this plasticizer is guided by the desired adhesion properties of the self-adhesive polyacrylate and by the degree of crosslinking as a result of the added polymer containing basic groups. Where the self-adhesive polyacrylates are of low molecular weight, chemical crosslinking of these polymers must additionally be undertaken. This is done by adding metal chelates, for example aluminium acetylacetonate, or other suitable substances.

Suitable plasticizers are, in principle, all compounds of low molecular mass that are compatible with the polymers. It should be borne in mind here that these plasticizers possess good skin compatibility. Compounds which have been found particularly suitable are fatty acid derivatives of glycerol, and also triacetin.
Admittedly, there are other known adhesives which alter their adhesion properties in the presence of water. Recall, for example, a postage-stamp adhesive which develops its adhesive properties only on wetting. This type of adhesive, however, has the critical disadvantage that it offers virtually no resistance to moisture and will break up if there is a surplus of water.
A pressure-sensitive adhesive in the context of the invention is, in contrast, highly water-resistant. In water of neutral pH it is virtually insoluble. Furthermore, it possesses outstanding adhesion properties even under very adverse conditions. It can be used everywhere that there is a requirement for effective and reliable adhesion on the skin over a prolonged period. It can be used with particular advantage for fixing cannulas and catheters, with electrodes for recording biosignals, with allergy testing plasters, with orthopaedic tapes and, last but not least, for plasters containing an active substance.

Example:

Preparing a self-adhesive film

209 g of self-adhesive, carboxyl-containing polyacrylate (Durotak™ 901-1051, 52 % g/g in ethyl acetate/n-heptane mixture)

4.8 g of polyacrylate containing basic amino groups (50 % g/g in ethanol) (Eudragit™ E 100)

8 g of triacetin

15 g of ethanol and

3.15 g of aluminium acetylacetonate (4 % g/g in ethyl acetate)

are stirred together and are coated as a 350 µm thick film onto a siliconized polyester sheet. The film is dried at 50°C for 30 minutes, after which it has a weight per unit area of 120 g/m^2.

Depending on the intended application, the dried film can be laminated with woven textile fabrics, knitted fabrics or nonwovens.

CLAIMS

1. A medical pressure-sensitive adhesive based on polyacrylates, having a minimal degree of tackiness in the state of application and whose tackiness increases upon action of moisture, due to reversible crosslinking, the adhesive comprising:

a) a self-adhesive polyacrylate copolymer containing at least 3 mol-per cent of acrylic acid or methacrylic acid subunits;

b) a polymer containing basic amino groups;

c) a plasticizer formed by triacetin or glycerol fatty acid ester; and

d) a metal chelate as crosslinking agent.

2. The medical pressure-sensitive adhesive according to Claim 1, comprising:

a) 91.1 % by weight of self-adhesive polyacrylate copolymer containing at least 3 mol-per cent of copolymerized acrylic or methacrylic acid;

b) 2.1% by weight of polymer containing basic amino groups;

c) 6.7% by weight of plasticizer; and

d) 0.1% by weight of a metal chelate.

3. The medical pressure-sensitive adhesive according to claim 1 or 2, wherein the polymer containing basic amino groups is a polyacrylate or polymethacrylate copolymer and contains, incorporated by polymerization, amino alcohol esters of acrylic or methacrylic acid.

4. The medical pressure-sensitive adhesive according to claim 1 or 2, wherein the polymer containing basic amino groups comprises dimethylaminoethyl methacrylate and neutral methacrylic esters.

5. The medical pressure-sensitive adhesive of any claims 1 to 4 wherein the metal chelate is aluminum acetylacetone.

6. Use of the pressure-sensitive adhesive according to any one of claims 1 to 5 for producing quick dressings, fixing plasters or self-adhesive electrodes.

7. Use of pressure-sensitive adhesive according to any one of claims 1 to 5 for producing medicated plasters.