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[54] **MEDICAL ADHESIVE SOLVENT COMPOSITION**

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[58] **Field of Search** 252/364; 424/184, 78, 45

[56] **References Cited**

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[57] **ABSTRACT**

A solvent composition is provided which will efficiently remove medical adhesives, particularly adhesives containing silicone resins, from skin and simultaneously replace body oils, and prepare the skin to receive subsequent applications of the adhesive. The solvent composition comprises a major effective amount of a liquid aliphatic hydrocarbon solvent fraction, preferably a C_8 to C_{11} aliphatic hydrocarbon fraction, a minor effective skin conditioning amount (generally comprising at least about 2 weight percent) of silicone fluid, and preferably, a minor effective amount of a flash point suppressant for the liquid aliphatic hydrocarbon fraction.

4 Claims, No Drawings

MEDICAL ADHESIVE SOLVENT COMPOSITION

This invention relates to solvents. In another aspect, this invention relates to a novel medical solvent and skin preparation composition. In still another aspect, this invention relates to a novel method of applying and removing prosthetic devices and the like from the skin.

Various medical prosthetic devices and body appliances are utilized which are affixed to the human body with a medical adhesive composition. Widely utilized body appliances include cosmetic body appliances for covering scars resulting from severe injuries, for example. These appliances are generally made of silicone rubber and utilize a silicone resin medical adhesive to affix them to the body surface. Prosthetic devices include male urinal devices which are affixed to the body with medical adhesives.

Thus, such medical prosthetic devices and body appliances must, when in use, be securely affixed to the skin of the patient. However, for medicinal and hygienic reasons, such devices and appliances must be periodically removed from the skin and then later reapplied thereto.

Since the conventional medical adhesive compositions will tenaceously adhere to both the prosthetic device, or body appliance and the skin, it is necessary to apply a solvent for the adhesive in order to remove the device or appliance from the skin. For example, when such device or appliance is made of silicone rubber and a silicone resin is utilized as the medical adhesive, it is conventional to use V.M. & P. naphthas or fluorocarbons as solvents therefor. The V.M. & P. naphthas are very harsh and tend to chap and blister as well as dry out the living tissue to which they are applied. The liquid fluorocarbons are expensive, and also tend to chap and dry out the skin. The deleterious effects on the skin which are imparted by the conventional solvents result (1) from the irritating effect the chemicals have upon the skin, and (2) because the solvents actually leach essential body fats and oils from the skin and leave them dry, chapped and scaly.

Therefore, one object of this invention is to provide a solvent composition which will effectively remove conventional medical adhesives from skin, but is nondeleterious to the human body.

A further object of this invention is to provide a novel solvent composition which will effectively remove medical adhesives from skin while simultaneously treating the skin to prevent drying and chapping.

A further object of this invention is to provide a novel solvent composition which will effectively remove silicone resin, medical adhesives and simultaneously treat the skin to prevent drying and chapping while preparing the skin to tenaceously receive a subsequent coating of silicone resin adhesive.

According to the invention, a solvent composition is provided which is particularly suitable for removing medical adhesives from the skin, and comprises a major effective amount of a liquid aliphatic hydrocarbon fraction as solvent, and a minor effective skin conditioning amount of a silicone fluid. In addition, the solvent composition preferably contains an effective proportion of a flash point suppressant for the liquid aliphatic hydrocarbons.

According to a preferred embodiment of this invention, the medical adhesive solvent composition is provided which comprises a major effective amount of an aliphatic hydrocarbon fraction which includes from about 30 to about 70 weight percent of a fraction consisting essentially of aliphatic C_8 and C_9 hydrocarbons and from about 30 to 70 weight percent of a fraction consisting essentially of aliphatic C_{10} and C_{11} hydrocarbons; from about 15 to about 25 weight percent of flash point suppressant; and at least about 2 weight percent of a silicone fluid. A particularly effective combination includes equal parts of the aliphatic C_8–C_9 fraction and the C_{10}–C_{11} fraction.

The composition of the subject invention can be utilized to remove conventional medical adhesives from the skin, and from other surfaces such as the skin contacting surfaces of prosthetic devices and body appliances. It is herein noted that the term "body appliance" as used in the scope of this invention includes any prosthetic device or body appliance which is attached to the body by medical adhesive compositions.

Furthermore, the composition of the subject invention is particularly effective for both removing silicone resin medical adhesive compositions from the skin, and preparing the skin for applications of such silicone resin medical adhesive compositions. The liquid aliphatic hydrocarbon solvent fraction is non-toxic and is not readily absorbed through human skin but yet functions to dissolve conventional medical adhesive compositions such as silicone resin adhesive compositions. In addition, the silicone fluid component functions not only to replace body fats and oils which have been leached by the solvent component, but also functions to prepare the skin to tenaceously receive a subsequent application of silicone resin.

The liquid aliphatic hydrocarbon fraction used in the solvent composition of this invention can have aliphatic components therewithin, containing from about 6 to about 15 carbon atoms. To avoid volatility extremes and yet utilize extremely effective solvent components for a medical adhesive, it is generally preferred that the liquid aliphatic hydrocarbons consist essentially of from C_8 to C_{11} straight and/or branched chain molecules. While some unsaturation can be present in the molecules, the preferred fractions contain a majority of paraffinic components. The percentage of the individual components can be varied as desired within the scope of this invention. For example, the aliphatic solvent fraction can comprise a majority of C_8's, C_9's, C_{10}'s, or C_{11}'s or various combinations thereof.

The most preferred liquid aliphatic hydrocarbon fraction which can be used in the solvent composition of this invention includes from about 30 to 70 weight percent of a first fraction of aliphatic C_8–C_9 (C_8's and/or C_9's) hydrocarbons combined with from about 30 to about 70 weight percent of a second fraction of aliphatic C_{10}–C_{11} (C_{10}'s and/or C_{11}'s) hydrocarbons. This fraction in combination with the other ingredients of the subject composition has been found to be particularly effective for removing medical adhesives, such as silicone resins and yet not impart deleterious effects to the skin. Generally, said first fraction will have a boiling range at 760 mm Hg within the range of from 200°–260°F, and said second fraction will have a boiling range at 760 mm Hg within the range of from 300° to 350° F.

The silicone fluid which can be used in the scope of this invention includes any of the liquid organosiloxane polymers which are nondeleterious to human skin, for

example, the methyl or phenyl polysiloxanes. The organisiloxane polymers which can be used in the composition of this invention have a wide range of viscosities of less than 1 (about 0.65) to several thousand centistokes. It is generally preferable to utilize an organosiloxane which has a viscosity in the range of from about 10 to about 100 centistokes. The silicone fluid is generally contained within the composition of the subject invention in amounts of at least about 2 weight percent thereof, and is most preferably contained in the composition of this invention within the range of about 2 to about 4 weight percent. Greater amounts (for example 10 weight percent) can be used if desired; however, it has been found that a silicone fluid content of from 2 to 4 weight percent is sufficient for most uses.

As described above, the silicone fluid functions in cooperation with the liquid aliphatic hydrocarbon component in the solvent composition of this invention. When the solvent composition of the subject invention is applied to an adhesive coating on animal skin, and particularly human skin, the silicone fluid readily coats the living tissue and functions to immediately replace body fats and oils which are leached therefrom by the action of the solvent. Thus, the silicone fluid efficiently coats the skin and combines with the skin to thereby prevent chapping and irritation due to loss of body fats and oils. This residue or coating of the silicone resin upon the skin which results from the application of the solvent composition of this invention thereto, tenaceously adheres to the skin and will not be removed by the application of mild soaps or detergents when removing the solvent-adhesive residue or when washing the skin after the solvent-adhesive residue has been wiped away.

The residue or coating which remains on the skin after application of the solvent composition of this invention imparts a special affinity to the skin for subsequent amounts of the silicone resin. Thus, it has been found that when the solvent composition of the subject invention is used to remove the silicone resin, subsequent applications of the silicone resin when reapplying the prosthetic device or body applicance will be received more uniformly on the skin and form a more efficient seal between the skin and the device or appliance than when conventional solvents are initially utilized.

In addition to the liquid aliphatic hydrocarbons and the silicone fluid components of the subject invention, a flash point suppressant or retarder is preferably added thereto. Any suitable flash point suppressant which is nondeleterious to the human body can be used in the scope of this invention. The preferred flash point suppressants are the halogenated lower alkyl hydrocarbons (about 1 to about 5 carbon atoms), such as for example, trichloroethane, tetrachlorodifluoroethane, trichloromonofluoromethane, trichlorotrifluoroethane, mixtures thereof and the like. The flash point suppressant is added to the solvent composition of this invention generally in amounts ranging from about 15 weight percent to about 25 weight percent thereof, depending upon the volatility of the particular liquid aliphatic hydrocarbon fraction used in said composition. Most preferably, the flash point suppressant is added in amounts of from about 18 to about 20 weight percent of the total composition. Generally, the flashpoint of the resulting composition then will be no less than 80° F as determined by ASTM D-56, and will generally be at least 100° F or more.

The components of the solvent composition of the subject invention can be admixed in any suitable manner. For example, it is convenient to add the silicone fluid and the flash point suppressant to the liquid aliphatic hydrocarbon and mix until a generally uniform composition is obtained.

The following example is given to further illustrate the scope of this invention and is not intended to limit the scope thereof:

EXAMPLE

A solvent composition of the subject invention was made by admixing 40 parts by weight of a first liquid aliphatic hydrocarbon mixture consisting essentially of C_8 and C_9 hydrocarbons (a mixture sold under the trademark of SOLTROL 10 by Phillips Petroleum Co.) and haVing the characteristics as set forth in Table I below, with 40 parts by weight of a second liquid aliphatic hydrocarbon fraction consisting essentially of C_{10} and C_{11} hydrocarbons (a mixture sold under the trademark of SOLTROL 100 by Phillips Petroleum Co.) and having the characteristics as set forth in Table II below.

TABLE I

Property	Typical	Test Method
Distillation, rec., °F at 760 mm		ASTM D-86
IBP	202	
10%	209	
50%	217	
90%	227	
DP	245	
API Gravity, 60°F	69.5	ASTM D-287
Specific Gravity, 60/60°F	0.7040	ASTM D-1298
Density at 60 F, lb/gal	5.860	ASTM D-1250
Vapor Pressure, psia at 100°F	1.9	ASTM D-323
Saybolt Color	+30	ASTM D-156
Sulfur Content, wt %	0.0033	ASTM D-1266
Acidity of Distillation Residue	neutral	ASTM D-1093
Copper Corrosion, 2 hrs at 212°F	1	ASTM D-130
Doctor Test	negative	ASTM D-484
Kauri-Butanol Value	28.2	ASTM D-1133
Nonvolatile Matter, g/100ml	none	ASTM D-1353
Kinematic Viscosity, cs at 32°F	0.976	ASTM D-445
cs at 100°F	0.633	

TABLE II

Property	Typical	Test Method
Distillation, evap., °F at 760 mm		ASTM D-86
IBP	315	
10%	317	
50%	327	
90%	331	
95%	335	
DP	343	
API Gravity at 60°F	58.7	ASTM D-287
Specific Gravity, 60/60°F	0.744	ASTM D-1298
20/4°C	0.740	Westphal Balance
Density at 60°F, lb/gal	6.19	ASTM D-1250
Flash Point, TCT, °F.	105	ASTM D-56
Color, Saybolt	+30	ASTM D-156
Corrosion, Copper Strip, 3 hrs at 212°F	1	ASTM D-130
Acidity of Distillation Residue	neutral	ASTM D-1093
Aniline Point, °F	179	ASTM D-1012

Next, 18 parts by weight by trichloroethane and 2 parts by weight of silicone fluid (a silicone fluid sold under the trademark of DC 200, by Dow-Corning and having from 10 to 100 centistokes viscosity) was added to the 80 parts by weight of the liquid aliphatic hydrocarbons to form the medical solvent composition of the subject invention.

This medical solvent composition was used to remove a medical adhesive (a silicone resin medical adhesive sold under the trademark of MEDICAL ADHESIVE "B" by Dow-Corning Medical Products Division). The medical adhesive was used in attaching to a human male a prosthetic device for the handling of urinary incontinence. This prosthetic device basically comprised a knit sheath impreganted with silicone rubber and is fully disclosed in my copending patent application Ser. No. 008,819, filed Feb. 5, 1971. The solvent was used to remove the device numerous times over a period of several months. In each instance, the solvent composition was applied during the removal operation and thereafter the skin area which was contacted by the solvent composition was washed with mild soap and water and the solvent residue containing the dissolved adhesive was flushed away. A layer of silicone fluid remained on the skin. When it was desired to reapply the prosthetic device, the silicone resin medical adhesive was applied over the skin which carried the silicone fluid coating, and the prosthetic device then applied thereto. During this several months period, no skin irritation whatsoever was observed and furthermore, the silicone resin adhesive was found to very effectively adhere to the treated area in an improved manner than when conventional solvents such as V.M. & P. naphthas are used to remove the medical adhesive.

While this invention has been described in relation to its preferred embodiments, it is to be understood that various modifications will be apparent to one skilled in the art from a reading of this specification, and it is intended to cover such modifications as fall within the scope of the appended claims.

I claim:

1. A skin conditioning medical adhesive solvent and skin preparation composition which consists essentially of:

a. about 2 to about 10 weight percent of liquid organosiloxane polymer effective to replace body fats and oils leached from the skin by solvent action:

b. about 5 to about 25 weight percent of a halogenated lower alkyl hydrocarbon flashpoint suppressant selected from the group consisting of trichloroethane, tetrachlorodifluoroethane, trichloromonofluoromethane, trichlorotrifluoroethane, and mixtures thereof; and

c. the balance of said composition which consists essentially of a solvent of from about 30 to about 70 weight percent of a mixture of $C_8 - C_9$ aliphatic hydrocarbons and from about 30 to about 70 weight percent of a mixture of $C_{10} - C_{11}$ aliphatic hydrocarbons;

said solvent not imparting deleterious results to the skin, said composition forming a more efficient seal with silicone resin medical adhesive between the skin and a prosthetic device or appliance upon reapplication thereof.

2. The composition of claim 1 wherein said flashpoint suppressant is trichloroethane.

3. The composition of claim 1 wherein said flashpoint suppressant is trichlorotrifluoroethane.

4. A medical adhesive solvent and skin preparation composition which consists essentially of 80 parts by weight of a solvent constituent which includes a liquid aliphatic hydrocarbon fraction which consists essentially of from about 30 to about 70 weight percent of a mixture of $C_8 - C_9$ aliphatic hydrocarbons and from about 30 to about 70 weight percent of a mixture of $C_{10} - C_{11}$ aliphatic hydrocarbons; 18 parts by weight of a halogenated lower alkyl hydrocarbon selected from the group consisting of trichloroethane, tetrachlorodifluoroethane, trichloromonofluoromethane, trichlorotrifluoroethane, and mixtures thereof; and 2 parts by weight of a liquid organosiloxane polymer.

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