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DERMAL PROTECTIVE COMPOSITIONS

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This invention relates to compositions and methods for rendering the skin repellent to hydrous and oily materials and more particularly to certain novel compositions adapted to topical application to provide a useful dermal protective coating.

This application is a continuation-in-part of our co-pending application Serial Number 718,156, filed February 28, 1958, now abandoned.

There are many situations in which the human skin is exposed to hydrous and/or oily materials which have undesirable effects. These effects may include corrosive or irritating action which can vary from slight reddening to actual damage such as vesication or ulceration; or the effects may be undesirable for reasons of cleanliness or appearance as, for example, soiling the skin with grease in mechanical operations or with ink in office work or printing.

It has long been known that the skin can be protected from the effects of the cleansing required to remove injurious materials, by the application of lotions, creams and other emollient compositions. These preparations of the prior art are intended to exert a beautifying, softening and lubricating effect in the skin and may even contain medicinal ingredients. Other compositions have been described which have the effect of producing a barrier film on the skin which will prevent absorption of harmful or cosmetically undesirable substances. However, the preparations heretofore known for the purposes described, while effective to some degree, have all suffered from certain disadvantages. Mere emollients fail to protect the skin from exposure to the injurious materials and only serve as palliative remedies afterwards. Barrier creams have been useful for certain specific conditions, but heretofore have failed to have broad general applicability. Furthermore, in maintaining personal hygiene, for example, by washing the hands, these compositions of the prior art are largely removed and repeated application is necessary. In some cases, the preparation may be oil-repellent, on application, but even a few drops of water alone will disrupt the film and nullify the effect. It is evident that under such conditions the benefits obtained are not lasting and exposure to irritants and colorants may not actually be affected at all since the protection is readily removed.

It has been proposed to incorporate particular ingredients in lotions, creams and other cosmetic materials for the purpose of providing residual protective barriers on the skin. Siloxanes have been so employed, as described in U.S. Patent No. 2,727,846, with considerable success; but these substances are themselves oily and when effective amounts are applied to the skin, the residue may give rise to an unpleasantly oily subjective sensation, particularly when applied as a dressing.

Liquid organo-silicon compounds such as the siloxanes are easily transferred from the hands by touch or slight abrasion. This is a serious drawback in that even traces of such substances may bring about contamination of

industrial equipment to such an extent as to interfere with proper process conditions. It is well-known that the presence of even traces of silicones will interfere with the action of adhesives, paints and protective coatings. Furthermore, to be effective, a coating of a siloxane must be applied which is virtually continuous and such a coating adversely impairs access of air and transpiration of moisture which is needed for the well-being of the skin. To obtain effective results, concentrations of silicone up to as high as 52 percent have been employed and these have been described as not always pleasing from a cosmetic viewpoint. The silicone-containing preparations should not be applied to even moderately inflamed skin, as pointed out by Suskind in Industrial Medicine and Surgery, v. 24, pp. 413–416, September 1955. It is noted that when water is applied to skin surfaces coated with siloxanes, the water is repelled to the extent that it forms into droplets having a low contact angle with the skin. The compositions of the present invention do not cause this and water spreads normally, thus giving a normal subjective effect; but nevertheless, the effects of aqueous irritants are prevented.

It is an object of this invention to provide a method for protecting the skin against injurious and undesirable materials. A further object is to provide a method for rendering the skin repellent to hydrous and oily materials. Another object is to provide compositions adapted to topical application to provide protective coatings for the skin, which compositions may include medicaments if desired. Other objects of the invention will become apparent from the disclosure hereinafter made.

In accordance with the above-stated and other objects of the invention it has been found that the skin is made oleophobic and resistant to aqueous materials, and protected from irritating and otherwise undesirable substances, by applying thereto a dermally compatible composition comprising a stable physiologically inert dispersion of a fluorocarbon elastomer in certain aqueous pharmaceutical extending media as hereinafter defined. The compositions of the invention provide a long-lasting, indiscernible film (when unpigmented) which is substantially free from the disadvantages of topical protective preparations heretofore known. Although extremely effective in its protective action, the film apparently does not adversely affect the transpiration of the skin.

Broadly speaking, compositions useful for the purposes of the invention are provided by incorporating a minor amount of a fluorocarbon elastomer dispersion into a major amount of an aqueous pharmaceutical extending medium of the aqueous emulsion type containing a thixotropic bodying agent. Preferably there is employed from about 0.3 to about 20 percent by weight of fluorocarbon elastomer solids, desirably in the form of a latex of a fluorocarbon elastomeric vinyl type polymer which is compatible with the human skin. The term "pharmaceutical extending medium" as used herein includes such preparations as the bases for lotions, creams, ointments and the like water-based preparations for topical application, which are sufficiently bodied so that the resultant cosmetic is not watery or thin but without limiting the viscosity range or composition solely to a single type of preparation. For the purpose of the invention, the viscosity of the products described and claimed herein is required to be not less than about 1000 centipoises when stirred at about 60 r.p.m. and may range upwardly to

about 5000 centipoises, when determined using a Brookfield viscometer at about 25° C. It appears to be self-evident that the physical appearance of such thixotropic preparations for topical application may range from that of a lotion through a flowable jelly, to that of petroleum jelly, i.e., fairly stiff but flowable under mechanical force.

Examples of hydrophilic pharmaceutical extending media are set forth in the Journal of the American Pharmaceutical Association, v. 30, pp. 196–201, 1941; in the Practicing Edition of the same journal, v. 1, 210, 1940; v. 3, pp. 231–234 and 324–326, 1942; and in the British Journal for Dermatology and Syphilology, v. 50, pp. 540–543, 1938. These bases consist of an aqueous suspension of one or more ingredients as well as dissolved materials and may require addition of thickening agents.

The thixotropic pharmaceutical extending medium must be compatible with water but also comprises various materials to impart additional properties to the product. As will be evident from the examples provided hereinafter the pharmaceutical extending medium consists of all the ingredients employed except for the latex-like dispersion of fluorocarbon elastomer. As such it may be produced separately and then blended with the aforesaid dispersion; or it may be prepared in such a fashion that the dispersion is incorporated in the extending medium during the preparation and is thereby blended with it.

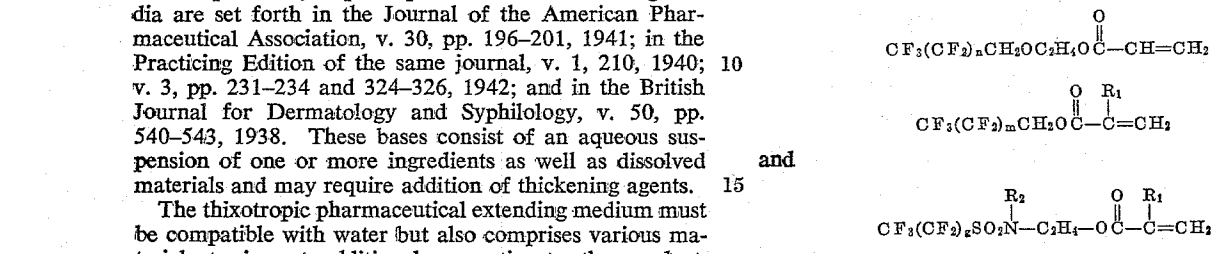
Illustrative of the types of materials which can be incorporated optionally in desired amounts for particular purposes are humectants, therapeutic ingredients, perfumes and colorants.

The pharmaceutical extending medium consists essentially of the aqueous base containing the thixotropic bodying agents or thickeners. In addition to water, the aqueous base may comprise alcohol or other solvents in amounts up to a few percent, not usually more than about 10 percent by volume.

Bodying agents include not only hydrophilic thickeners such as methyl cellulose, polyethylene glycols and hydrophilic gums such as gum tragacanth and gum kharaya but also hydrophobic materials such as stearic acid, cetyl alcohol, lanolin, petrolatum, cholesterol which are more or less waxy, as well as solids such as bentonite. In general when hydrophilic thickening agents are employed, it is not necessary to include emulsifying agents. However, when the hydrophobic or solid thickening agents are employed, some emulsifying or pentizing agent is usually necessary over and above any such agent which may be present in the dispersion of fluorocarbon elastomer. The manner in which these are formulated is further exemplified hereinbelow. In the selection of these ingredients, as well as where medicaments or therapeutic ingredients are added, it is necessary to avoid use of materials which tend to flocculate the colloidal particles of fluorocarbon elastomer, for example, substances rendering the mixture either strongly acidic or strongly basic, or substances giving high ionic strength.

The significant and critical film-forming and protective ingredient of the compositions of the invention is the fluorocarbon elastomer, which is conveniently supplied by incorporating into the thixotropic pharmaceutical extending medium a suitable volume of a latex or other dispersion of a fluorine-containing polymer. Such polymers are fluorochemical elastomers, which are formed by vinyl-type polymerization, i.e. free radical catalyzed polymerization of terminally unsaturated monomers. The useful polymers may be further described as oleophobic and hydrophobic physiologically inert stable fluorine-containing elastomeric vinyl-type polymers in which from 10 to about 75 percent of the hydrogen directly attached to carbon has been replaced by fluorine and which are characterized by a glass transition temperature below about 40° C. Elastomers of this type have molecular weights ranging upward from 20,000 to 1,000,000 and even higher. They are available by processes known to the art as latices containing up to about

40 percent polymer solids and the amounts thereof to be added to the pharmaceutical extending medium are calculated on the basis of total solids by dry weight. Illustrative fluorocarbon elastomers of the type preferred for the compositions of the invention are those selected from the group consisting of polymers of a monomer of the formula:



and

in which R_1 represents a member of the group consisting of hydrogen and the methyl radical, R_2 represents a member of the group consisting of ethyl and propyl radicals, n has the numerical value 0 to 2, m has the numerical value 1 to 6 and g has the numerical value 3 to 11, and the copolymer of vinylidene fluoride and trifluorochloroethylene containing from about 35 to 65% of vinylidene fluoride by weight.

Examples of the class of fluorocarbon monomers from which the preferred fluorocarbon elastomers are produced include the following: 1,1-dihydroperfluorobutoxyethyl acrylate, 1,1-dihydroperfluorobutyl acrylate, 1,1-dihydroperfluoropropoxyethyl acrylate, 1,1-dihydroperfluoropropyl methacrylate, 1,1-dihydroperfluoroethoxyethyl acrylate, 1,1-dihydroperfluorooctyl acrylate, 1,1-dihydroperfluorohexyl acrylate, 1,1-dihydroperfluorobutyl methacrylate, N-ethylperfluorooctanesulfonamidoethyl acrylate, N-propylperfluorooctanesulfonamidoethyl methacrylate, N - ethylperfluorobutanesulfonamidoethyl acrylate and copolymers including 10 percent by weight of internal plasticizers such as octadecyl methacrylate, dodecyl acrylate and decyl methacrylate with N-ethyl-perfluoro-dodecanesulfonamidoethyl methacrylate.

As used herein, the terms "polymer" or "elastomer" refer to homopolymers, copolymers or plasticized polymers, or mixtures thereof. As noted, fluorocarbon elastomers are employed which have a "glass transition temperature" (Tg) below about 40° C., as determined by the method described by Wiley et al., J. Poly. Sci. v. 5, No. 5, pp. 609–614, October 1950. Plasticizing agents which are non-toxic and compatible with the skin can be added during formation of the latex or by other suitable means, to lower the glass temperature of elastomers of the class described which have a glass temperature above this point. Such plasticizers include inert substances such as N-ethyl perfluorooctanesulfonamido ethanol, as well as internal plasticizers which are added as comonomers, for example, octadecyl acrylate.

Dispersion of the fluorocarbon elastomer for use in the compositions of the invention can also be accomplished by other methods as, for example, by emulsifying a solution of the polymer in a suitable solvent; however, it is preferred to employ latices prepared by emulsion polymerization using catalysts and emulsifying agents which possess very low toxicity, so that the latices are physiologically inert and compatible with the human skin, and therefore can be incorporated directly with the pharmaceutical extending medium without danger of causing side reactions such as irritation even to sensitive skins. Since some people are hypersensitive, for example, to many emulsifying agents, it is not possible to avoid all reactions to ingredients of these latices in all cases, but by selection of the emulsifying agent and other ingredients, materials known to be likely to cause irritation can be avoided.

The protective coating is applied to the skin by spreading the fluorochemical elastomer latex-containing lotion in a more or less uniform layer on the clean skin over all

of the area to be protected, and permitting it to dry. As a result, there is produced over the entire treated area of the skin, a firmly adherent, non-tacky and non-transferring protective polymer layer, which is repellent to aqueous and oily materials as well as to many ordinary solvents. The coating is invisible and substantially continuous; and is pervious to air and vapors, for example, water vapor. Flexing of the skin does not result in cracks or discontinuities in the protective coating as might be expected; instead, there appears to be an elastic stretching of the fluorocarbon polymers giving a continuously conforming coating of the protective polymer which even tends to enhance the suppleness of the skin.

The purposes for which the protective coatings of the invention can be used are extremely numerous. As hereinabove stated, the compositions have cosmetic uses as well as practical uses as barrier films. Furthermore, the use of the compositions of the invention tends to promote healing of superficial abrasions and irritation of the skin. Other uses embodying the oil and water repellent skin coating of the invention are at once apparent to the art. Thus, by suitable incorporation of finely divided pigments such as titanium dioxide, rouge, prepared chalk, talc and the like in a lotion or cream base of this type, cosmetic preparations adapted to covering the skin for esthetic or screening purposes can be prepared. By adding ultraviolet screening agents such as glyceryl p-aminobenzoate or beta-methyl-umbelliferone a durable sun-burn preventive lotion is made possible which is not removed by exposure to water. Such a lotion has a further advantage in that oily contamination of the water as occasionally occurs along beaches and in pools is repelled and does not soil the body. Other possible embodiments of the invention, such as the addition of insect repellents, for example, dimethyl phthalate, diethyl toluamide and the like, to the fluorocarbon elastomer-containing fundamental composition to provide insect-repellent preparations having the desirable properties set forth herein, will be apparent to the art.

By incorporating compatible therapeutic agents into pharmaceutical extending media of the type herein described and containing fluorocarbon elastomers dispersed therein, medicaments having advantageous topical therapeutic action are provided. Thus, for example, non-ionic mercurial or other bactericides such as hexachlorophene or the like can be used to reduce the bacterial flora on the hands. The compositions of the invention also furnish relief in and assist in the treatment of such conditions as are aggravated by aqueous or oily materials as, for example, contact allergies such as ivy poisoning, diaper rash and the like.

The aqueous compositions containing fluorocarbon elastomers comprehended within the scope of the invention can function as operative means for providing an effective protective skin barrier film even in the presence of detergents. Repeated washing or scrubbing with a detergent and water are necessary for complete removal of the film, which consequently has a comparatively long duration of effectiveness.

The following examples in which parts are by weight except as otherwise specified demonstrate the best mode contemplated for practicing the invention and will further illustrate the compositions of the invention and the method for protecting the skin. These examples are to be regarded as illustrations only, rather than limiting. Viscosities are determined on a Brookfield viscometer using a number 4 spindle at room temperature (about 25° C.) and 60 r.p.m. and are expressed in centipoises.

EXAMPLE 1

A simple unperfumed hand lotion containing poly-1,1-dihydroperfluorobutyl acrylate was prepared by mixing about 3 parts of an aqueous 30 percent poly-1,1-dihydroperfluorobutyl acrylate latex (containing about 1 percent sodium lauryl sulfate as an emulsifier) and 80 parts of water with about 5 parts of pearl grade stearic acid with

heating and stirring, followed by neutralization to a pH of about 6.0 with potassium carbonate and addition to the hot, stirred emulsion of about 12 parts of polyethylene glycol monostearate having a melting point of about 33–38° C. and believed to have the approximate formula:

$$HO(CH_2CH_2O)_9—CH_2CH_2O—\overset{O}{\overset{\|}{C}}—C_{17}H_{35}$$

(available commercially from Glyco Products Co. as polyethylene glycol 600 monostearate). The emulsion became thick and creamy and on cooling was highly suitable as a hand cream. The viscosity was about 3300 centipoises. When applied to the hands it imparted a smooth feeling to the hands. The protective action was shown by dipping the protected area into xylene and into methyl ethyl ketone, shaking off excess solvent and permitting the wetted area to dry. In neither case was there evidence of the whitening of the surface of the skin occasioned by removal of the oils therefrom which is observed when untreated hands are rinsed in these and other solvents. Even after washing the hands with soap and water there was substantially no effect of the solvents on the skin when again drenched in these two solvents. A hand lotion containing the same hydrophilic pharmaceutical base and prepared similarly, employing only water instead of the latex, failed to give any protection to the hands against solvents and washed off readily with soap and water.

EXAMPLE 2

Another lotion within the scope of the invention was prepared by adding 3.0 parts of a latex of poly-1,1-dihydroperfluorobutyl acrylate containing 30 percent by weight of polymer solids (and containing about 1 percent sodium stearate as emulsifier) to an emulsion of 0.5 part of triethanolamine and 10.0 parts of diethylene glycol monostearate in 86.5 parts of distilled water heated to 75° C. When about 3 ml. of this lotion was rubbed on the hands and allowed to dry, the hands were protected against the solvent action of methyl ethyl ketone even after washing the hands thoroughly three successive times with soap and hot water.

The protective action of the same lotion was compared with that of two commercial protective or barrier creams which are believed to be, respectively, combinations of methyl cellulose with a vegetable wax and with stearic acid. Each preparation was rubbed on the skin of the forearm of a test subject, in marked adjacent areas of approximately equal size, about 5×5 cm. To furnish visual evidence of the effectiveness of each, a solution of 1.0 g. of Sudan Red (an oil-soluble red dyestuff which strongly stains unprotected human skin) in 100 cc. of a mixture of equal volumes of heptane and xylene was applied to the area of the skin being tested and then removed by blotting off with absorbent tissue after about 1 minute. The amount of staining of the skin thus produced indicated the effectiveness of the protection afforded. The composition of the present invention as described above and the two commercial preparations gave good protection immediately after application as shown by the very faint staining evident after removal of excess dyestuff, while the unprotected portion of the skin was dyed bright red. After washing the areas of application with soap and warm water, and again temporarily applying the dye solution as before, the area covered by the lotion of the invention showed faint staining. The other areas including those where the two commercial preparations had been applied showed marked straining.

EXAMPLE 3

Another composition was prepared by adding 3.0 parts of an aqueous latex of poly-1,1-dihydroperfluorobutyl acrylate containing 33 percent polymer solids (having contained therein about ½ percent polyoxyethylene glycol octyl phenyl ether as emulsifier), with stirring, to 100 parts of a solution of 0.5 part of a polyacrylic acid (available commercially as "Carbopol 934" from the B. F. Goodrich Chemical Co.), in 95.5 parts of distilled water,

followed by addition of 1 part of triethanolamine. When applied to the skin by rubbing in the usual manner, an effective protective coating was produced. When tested by applying a one-half percent solution of Sudan Red in a mixture of equal volumes of xylene, heptane and methylethyl ketone, the skin in the treated area was substantially unaffected. Immersing the treated areas in water did not affect the protection against subsequent staining by the dye solution. After washing the treated area with soap and warm water a substantial degree of protection remained.

When applied to the hands, the protective coating formed by this composition made possible easy removal, with soap and water, of the stains produced by duplicating ink used in the "Ditto" process.

EXAMPLE 4

Preparation of a lanolin-containing lotion according to the invention.

A mixture of 60 parts of water and 1 part of stearic acid was heated until the latter melted and the mixture was then stirred slowly and brought to about pH 7 by addition of triethanolamine. The resulting neutralized solution was heated to about 90° C. and 1 part of melted lanolin was added with rapid stirring which was continued until the batch had cooled to about 40° C. A mixture of 3 parts of an aqueous latex of poly-1,1-dihydroperfluorobutyl acrylate containing 33 percent polymer solids prepared using sodium lauryl sulfate as emulsifier, and 20 parts of 2 percent Carbopol 934 solution in water was added to the batch with slow stirring followed by 15 parts of ethanol and a sufficient amount of triethanolamine to bring the lotion to about pH 6.0. Six drops of a perfume concentrate were further stirred in. This produced a soft, smooth, white lotion in which the lanolin was thoroughly dispersed, which had excellent texture and an agreeable odor. The viscosity is about 2200 centipoises. When applied to the hands, it gave good protection against staining by organic solvent solutions of Sudan Red, both before and after washing the hands. The hands subjectively felt pleasant and soft.

EXAMPLE 5

Using the same ingredients set forth in Example 4 but replacing the latex employed therein with 3.3 parts of an aqueous latex of polymerized N-propyl perfluorooctanesulfonamidoethyl acrylate containing 30.4 percent of polymer solids, a hand lotion was obtained which provided the skin with excellent protection against staining by a one-half percent solution of Sudan Red in mixed xylene, heptane and methylethylketone.

EXAMPLE 6

Employing the same pharamaceutical base formulation as set forth in above Example 4, lotions were prepared containing aqueous latices of fluorocarbon elastomers in greater amounts. In this way lotions containing respectively 2 percent of poly-1,1-dihydroperfluorobutyl acrylate and 5 percent of poly-N-propylperfluorooctanesulfonamidoethyl acrylate were prepared. The larger content of fluorocarbon elastomer in the compositions of the invention, as for example 5 percent or over, may be desirable for certain applications. It was found, for example, that when the lotion containing 5 percent of fluorocarbon elastomer dispersed therein was applied to the hands, oil paint residues thereafter accumulating on the hands were readily washed off using a small amount of solvent and soap and water, the skin remaining supple and pleasant to the touch. Under comparable conditions, but where the skin was untreated, pigment from the paint resisted all efforts at removal and remained imbedded in the skin for several days until worn off by natural desquamation of the skin.

A composition containing 5 percent of poly-N-propyl perfluorooctanesulfonamidoethyl acrylate dispersed therein as set forth above was tested using rabbits to determine how effectively it protected against the irritating effects of 2 percent aqueous sodium hydroxide, 4 percent aqueous sulfuric acid, 2 percent phenol in benzene and 4 percent aqueous phenol.

The abdominal skin of the rabbit was clipped and areas were marked off and divided into equal halves thereon with a soft wax pencil. One half of each area was designated as a control area, and the other half was treated with the protective lotion. After the lotion dried, cotton swabs soaked in each of the above-named irritating substances were streaked across the marked skin areas, and the resulting wet areas permitted to dry, several rabbits being employed to test each irritant. The results were read after 24 and 72 hours. It was found that the protected areas showed only slight reddening, whilst the control areas were strongly irritated, showing marked erythema.

In a similar test, employing 1 percent croton oil in benzene as an irritant, the treated areas were substantially unaffected, whilst the control areas were very strongly irritated.

EXAMPLE 7

A series of tests was made of lotions prepared using the hydrophilic pharmaceutical base of Example 4 incorporating a variety of fluorochemical polymers in amounts sufficient to give 5 percent polymer solids in the resultant lotions, which were then scored on a visually estimated scale of 0 to 5 for increased staining by 0.5 percent solution of Sudan Red in an equal volume mixture of methylethyl ketone, heptane and xylene during 15 seconds exposure. On this scale, 0.2 indicates barely discernible coloring; 0.5 indicates slight staining in skin crevices; 1.0 indicates definite staining in skin crevices; 1.5 indicates definite staining in skin crevices with slight staining on skin plateaus; 2.0 indicates definite staining in crevices and on plateaus; 3.0 indicates heavy staining in crevices and definite staining on plateaus; 4.0 indicates heavy staining in plateaus and crevices; 5.0 indicates the marked, undifferentiated staining characteristic of unprotected skin. A score below about 2 would be considered excellent protection; scores up to about 3 indicate somewhat less efficient but still significant and useful protective characteristics.

Certain of these latices were prepared using emulsifying agents other than those specified in Example 4, as indicated in the following table which shows the scores achieved in this series of tests.

Table I

Test	Monomer	Emulsifier	Average score	T_g, ° C.
A	N-ethyl-perfluorooctane-sulfonamidoethyl acrylate	(a)	0.2	+1
B	N-propyl-perfluorooctane-sulfonamidoethyl acrylate	(d)	0.5	+10
C	N-propyl-perfluorooctane-sulfonamidoethyl methacrylate	(a)	0.75	[2]+10
D	N-ethylperfluorooctane-sulfonamidoethyl methacrylate	(a)	1.0	[1]+30
E	25:75 N-ethylperfluorooctane-sulfonamidoethyl methacrylate and octadecyl methacrylate	(a)	2.5	−3
F	1,1-dihydroperfluorobutyl acrylate	(e)	0.5	−30
G	1,1-dihydroperfluoropropyl acrylate	(c)	1.0	−26
H	1,1-dihydroperfluorohexyl acrylate	(c)	0.5	−39
I	1,1-dihydroperfluorohexyl methacrylate	(c)	3.0	+48
J	1,1-dihydroperfluoroethoxy ethyl acrylate	(c)	2.0	−67
K	50:50 vinylidene fluoride and trifluorochloroethylene	(b)	1.5	−6

a Potassium N-ethyl-N-perfluorooctanesulfonamido glycinate.
b Equimolar copolymer latex containing the potassium salt of a chlorofluorinated acid as emulsifier.
c Polyethylene glycol octyl phenyl ether, available commercially under the trademark name "Triton X-100".
d Octylphenoxyhexadecaethylene glycol.
e Commercial "Ivory" soap flakes.
[1] T_g for this polymer is about 65° C; latex as prepared for composition of this example contained about 20 per cent of N-ethyl perfluorooctanesulfonamido ethanol as an added plasticizer, which reduced T_g to value shown.
[2] Side chain melting point. This polymer is internally plasticized by T_g well below this value.

It is evident that excellent protection is furnished by the lotions comprising latices of fluorochemical elastomers with low T_g. Stiffer polymers such as the methacrylate of Test I score 3.0. Such elastomers can be plasticized and then when used in the compositions of the invention give results comparable to the other preparation shown. Example F illustrates the preparation of a lotion designed to avoid hypersensitivity to such an emulsifying agent as sodium lauryl sulfate. It is preferred to employ lotions having a low score in this test because of their relatively greater efficiency. It is also found that low-scoring lotions tend to preserve their protective action better after washing than do the higher scoring materials.

It is noted that fluorocarbon elastomers suitable for incorporation into the compositions of the invention contain fluorine occupying the positions of from about 10 percent to about 75 percent of the carbon-attached hydrogen atoms therein; the preparations designated E and K in the preceding table illustrate compositions of the invention in which the fluorocarbon elastomers used approach these respective points.

EXAMPLE 8

A preparation is made as described in Example 4 in which the 15 parts of ethanol is replaced by 15 parts of water. The resulting lotion is of a pleasing creamy consistency with a viscosity of about 1800 centipoises. The lotion is found to dry somewhat more slowly than that of Example 4 but affords comparable protection.

EXAMPLE 9

A topical preparation embodying the compositions of the invention and containing an antibacterial agent is prepared as follows: to a lotion prepared according to the procedure of Example 6, and containing 5 percent of poly-N-propylperfluorooctanesulfonamidoethyl acrylate, is added 1 percent by weight of finely divided hexachlorophene (3,5,6,3′,5′,6′,-hexachloro-2,2′-dihydroxydiphenyl methane), with thorough mixing to obtain a substantially homogeneous dispersion.

The useful results obtained when the preparation is applied to the hands are demonstrated by tests showing the extent of bacterial contamination of the skin after application, as follows: The germicidal lotion of this example, designated "A," is compared with a similar preparation containing 1 percent of hexachlorophene but in which the fluorochemical elastomer is omitted, designated "B"; and also with other treatments in which no hexachlorophene is employed. In one of these the hands are thoroughly washed with liquid soap and in another the lotion containing fluorochemical elastomer is compared with the lotion base alone. A human subject is employed, who is at the same time engaged in his usual activities in supervising applied research work.

The subject's hands, after the appropriate treatment, and at intervals thereafter, are pressed firmly against a sterile culture medium (Difco Nutrient Agar B1) in a glass dish of suitable size and the thus inoculated medium is incubated at 28° to 30° C. for about 30 to 36 hours. After this time the colonies of bacteria are visually discernible and are counted. The number of such colonies is a direct measure of the contamination of the hands by bacteria. It is, of course, evident that when the hands are grossly contaminated, the number may vary widely. Thus in parallel tests each hand is impressed on agar plates immediately after thorough washing with soap and warm water and again after one hour. Although the bacterial colony count on either hand is only about 325 immediately after washing, the left hand shows 2355 colonies and the right hand 1606 one hour later. In another test the left hand is coated with the fluorochemical elastomer lotion of Example 6 and the right hand with the hydrophilic base alone, containing no fluorochemical, and neither preparation containing any added germicide. It is found that immediately after application of these

lotions the bacterial colony count varies from about 900 to about 2000 whereas after one hour the count is more uniform at 1139 and 1194.

The two compositions designated A and B are applied to the left and right hands respectively after thorough washing. Agar plates are inoculated and incubated and bacterial colony counts are made as above immediately after treatment, after one hour and after 11 hours. Normal activities are pursued during the test period so that the hands are soiled and washed several times. The right hand, to which preparation B containing no fluorochemical has been applied, shows 1, 73 and 905 colonies at the respective times specified, whereas the left hand (treated with the germicidal lotion A of this invention) shows 0, 6 and 584 colonies respectively. The results indicate that the effectiveness of the germicide has been maintained for at least one hour and some residual effect appears to remain even after 11 hours.

What is claimed is:

1. A composition adapted for topical application which consists essentially of a water miscible pharmaceutical extending medium having an aqueous base and containing a dispersed bodying agent and having homogeneously dispersed therein a latex-like dispersion of an oleophobic and hydrophobic physiologically inert stable fluorine-containing elastomeric vinyl polymer in which from 10 to about 75 percent of the hydrogen directly attached to carbon has been replaced by fluorine and which elastomer is characterized by a glass transition temperature below about 40° C., in amount sufficient to provide from about 0.3 to 20% by weight of said elastomer in said composition, said extending medium being compatible with said latex-like dispersion.

2. A composition according to claim 1, in which the fluorocarbon elastomer is poly-N-propylperfluorooctanesulfonamidoethyl acrylate.

3. A composition according to claim 1, in which the fluorocarbon elastomer is poly-1,1-dihydroperfluorobutyl acrylate.

4. A composition according to claim 1, in which the fluorocarbon elastomer is poly-N-ethyl-perfluorooctanesulfonamidoethyl acrylate.

5. A composition according to claim 1, in which the fluorocarbon elastomer is poly-N-ethylperfluorooctanesulfonamidoethyl methacrylate.

6. A composition according to claim 1, in which the fluorocarbon elastomer is poly-1,1-dihydroperfluoropropyl acrylate.

7. A composition according to claim 1, in which the fluorocarbon elastomer is poly-1,1-dihydroperfluorohexyl acrylate.

8. A composition according to claim 1, in which the fluorocarbon elastomer is 1,1-dihydroperfluoroethoxyethyl acrylate.

9. A composition according to claim 1, in which the fluorocarbon elastomer is poly-1,1-dihydroperfluorohexyl methacrylate.

10. A composition according to claim 1, in which the fluorocarbon elastomer is a copolymer of vinylidene fluoride and trifluorochloroethylene.

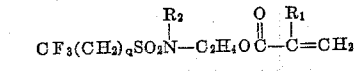
11. A composition according to claim 1, in which the fluorocarbon elastomer is a copolymer of N-ethylperfluorooctanesulfonamidoethyl methacrylate and octadecyl methacrylate.

12. A composition adapted for topical application which consists essentially of a latex-like dispersion of a physiologically inert fluorocarbon elastomer characterized by having a glass transition temperature below about 40° C. and selected from the group consisting of polymers of a monomer of the formulae:

$$CF_3(CF_2)_nCH_2OC_2H_4OC(=O)-CH=CH_2$$

$$CF_3(CF_2)_mCH_2OC(=O)-C(R_1)=CH_2$$

and

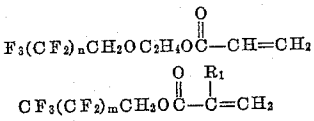


in which R_1 represents a member of the group consisting of hydrogen and the methyl radical, R_2 represents a number of the group consisting of ethyl and propyl radicals, n has the numerical value 0 to 2, m has the numerical value 1 to 6 and q has the numerical value 3 to 11, and the copolymer of vinylidene fluoride and trifluorochloroethylene containing from about 35 to 65 percent of vinylidene fluoride by weight homogeneously dispersed in a water-miscible pharmaceutical extending medium having an aqueous base and containing a dispersed bodying agent, the amount of latex-like dispersion of elastomer being sufficient to provide from about 0.3 to about 20 percent by weight of said polymer in said composition.

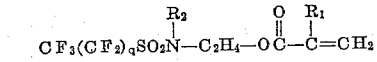
13. A composition adapted for topical application which consists essentially of a water miscible pharmaceutical extending medium having an aqueous base and containing a dispersed bodying agent and having homogeneously dispersed therein a latex-like dispersion of an oleophobic and hydrophobic physiologically inert stable fluorine-containing elastomeric vinyl polymer in which from 10 to about 15 percent of the hydrogen directly attached to carbon has been replaced by fluorine and which elastomer is characterized by a glass transistion temperature below about 40° C. in amount sufficient to provide from about 0.3 to 20 percent by weight of said elastomer in said composition, said extending medium being compatible with said latex-like dispersion and the said composition having a viscosity in the range of about 1000 to 5000 centipoises when determined at 60 r.p.m. and 25° C. using a Brookfield viscometer.

14. A composition adapted for topical application which consists essentially of a latex-like dispersion of a fluorocarbon elastomer characterized by having a glass

transition temperature below about 40° C. of the group consisting of polymers of monomers of the formula:



and



in which R_1 represents a member of the group consisting of hydrogen and the methyl radical, R_2 represents a number of the group consisting of ethyl and propyl radicals, n has the numerical value 0 to 2, m has the numerical value 1 to 6, and q has the numerical value 3 to 11, and the copolymer of vinylidenefluoride and trifluoro chloroethylene containing from about 35 to 65 percent of vinylidene fluoride by weight, homogeneously dispersed in a water-miscible pharmaceutical extending medium having an aqueous base and containing a dispersed bodying agent, the amount of latex-like dispersion of elastomer being sufficient to provide from about 0.3 to about 20 percent by weight of said polymer in said composition, the said composition having a viscosity in the range of about 1000 to 5000 centipoises when determined at 60 r.p.m. and 25° C. using a Brookfield viscometer.

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