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(71) Applicant(s)
Dow Corning France S.A.

(72) Inventor(s)
Gary Lord; Marie-Therese Valencia; Xavier Thomas

(74) Agent/Attorney
Shelston IP,Level 21,60 Margaret Street,SYDNEY NSW 2000

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(71) Applicant *(for all designated States except US)*: **DOW CORNING FRANCE S.A.** [FR/FR]; 20 boulevard E. Deruelle, F-69003 Lyon (FR).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **LORD, Gary** [GB/FR]; Les Capucines, Chemin de la Ponchette, F-06330 Roquefort Les Pins (FR). **VALENCIA, Marie-Thérèse** [FR/FR]; 365 Chemin des Martelly, F-06580 Pegomas (FR). **THOMAS, Xavier** [FR/FR]; 7 bis avenue de Lerida, F-09000 Foix (FR).

(74) Agents: VANDAMME, Luc, J. et al.; Dow Corning Limited, Cardiff Road, Barry CF63 2YL (GB).

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(54) Title: SCAR TREATMENT COMPOSITION

(57) Abstract: A composition comprising 1-25 wt.% of a silicone gum, 1-40 wt.% of a silicone fluid having a viscosity of 10 to 60,000 mm^2/sec, 1-35 wt.% of a silicone wax and 20-90 wt.% of a volatile silicone fluid having a viscosity up to and including 5 mm^2/s at 25 °C can be used for the treatment of scars resulting from injury or surgery.

SCAR TREATMENT COMPOSITION

The present invention relates to a novel composition comprising a silicone fluid, a silicone gum, a silicone wax and a volatile silicone. This composition can be used for the treatment of scars resulting from injury or surgery.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

Scars resulting from injury or surgery are undesirable both cosmetically and functionally. Cosmetically, scar tissue is often viewed as unsightly. Functionally, scar tissue often lacks features of undamaged skin such as a normal sense of touch and complete skin integrity.

Numerous methods have been developed to treat and/or prevent scars including surgical treatment, aftercare coverings, pressure treatment, oils, creams, greases, wound dressings such as hydrogel or silicone gels, collagen implantation and laser ablation. For instance, United States Patent Number 4,991,574 teaches a surgical dressing comprising a sheet of silicone gel having a wound-facing surface and, laminated to the other surface, a film of silicone elastomer. This dressing, however, is cumbersome for patients to apply and is difficult to adhere and maintain adherence on certain parts of the body.

Likewise, United States Patent Number 5,741,509 teaches a wound dressing comprising a blend of silicone fluid, fumed silica and a volatile diluent. This patent teaches that the volatile diluent reduces the consistency of the composition so that it can be applied to a wound without producing injury or discomfort. When the volatile diluent evaporates, a stiff cream having increased wound

adhesion is left. This material, however, is tacky and fails to provide sufficient occlusivity.

The present invention relates to a scar treatment composition that forms films on the skin which are substantive, semi-occlusive, non-tacky, cosmetically acceptable and easy to apply and remove.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

Summary of the Invention

We have now discovered that these properties are delivered by a composition comprising 1-25 wt. % of a silicone gum, 1-40 wt. % of a silicone fluid having a viscosity of 10 to 60,000 mm^2/s, 1-35 wt. % of a silicone wax and 20-90 wt. % of a volatile silicone fluid having a viscosity up to and including 5 mm^2/s.

According to a first aspect, the present invention provides a composition suitable for the treatment of scars comprising:

1-25 wt. % of a silicone gum;

1-40 wt. % of a silicone fluid having a viscosity of 10 to 60,000 mm^2/s at 25°C ;

1-35 wt. % of a silicone wax; and

20-90 wt. % of a volatile permethylsilane or silicone fluid having a viscosity up to and including 5 mm^2/s at 25°C.

According to a second aspect, the present invention provides a method of forming a film on a substrate comprising:

(A) mixing components comprising:

1-25 wt. % of a silicone gum;

1-40 wt. % of a silicone fluid having a viscosity of 10 to 60,000 mm^2/s at 25°C ;

1-35 wt. % of a silicone wax; and

20-90 wt. % of a volatile permethylsilane or silicone fluid having a viscosity up to and including 5 mm^2/s at 25°C;

(B) applying the mixture formed in (A) to a substrate; and

(C) allowing the volatile permethylsilane or silicone fluid to evaporate and thereby deposit a film on the substrate.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

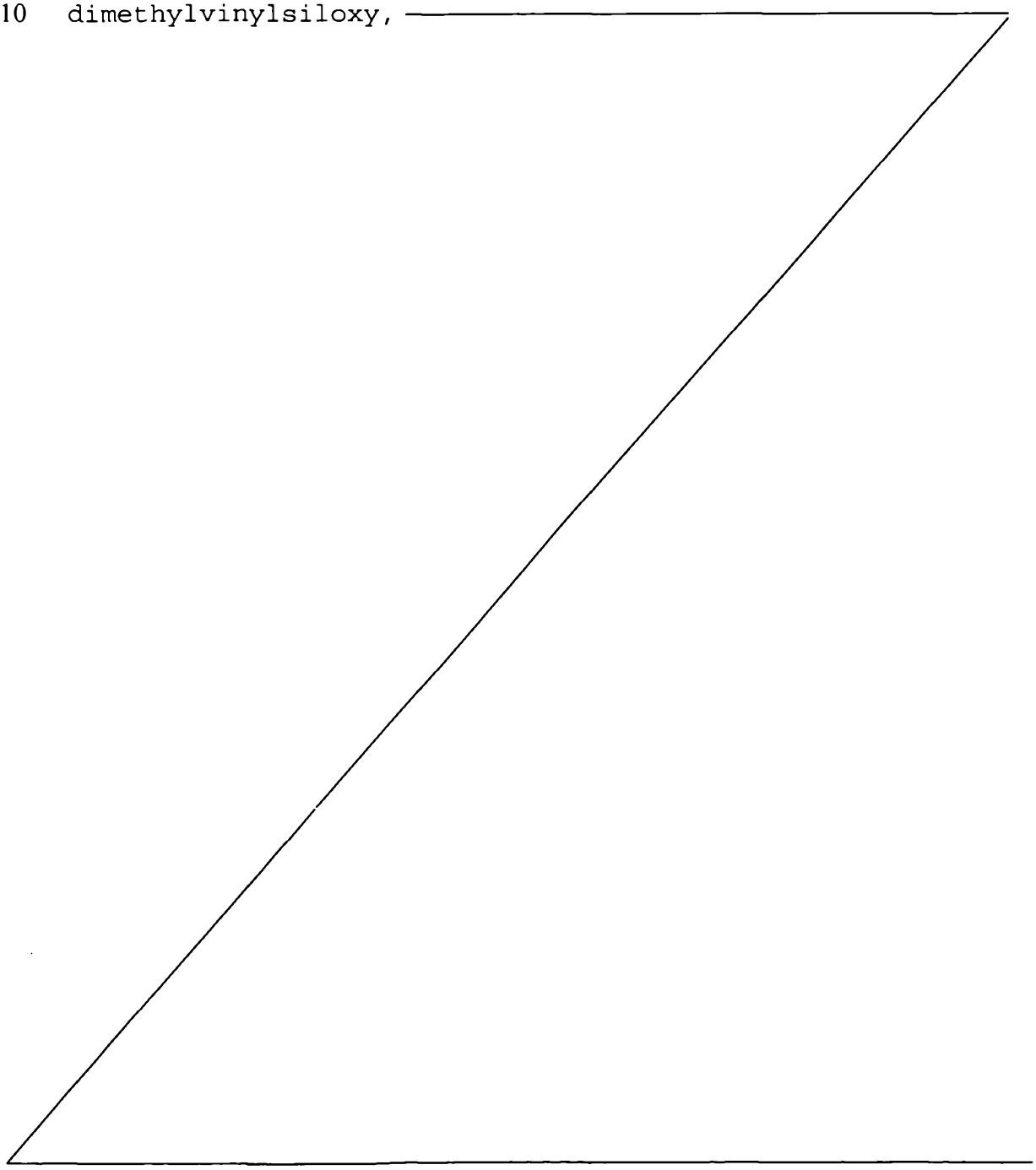
These compositions can be used for the treatment of scars resulting from injury or surgery.

Detailed Description of the Invention

The compositions of the present invention have numerous properties which render them useful for forming films on the skin. These include, for example, the films are substantive such that they do not smear, transfer to clothing or exhibit cold flow. Similarly, the films are semi-occlusive such that they provide an emollient and moisturizing effect. Additionally, the compositions are aesthetically pleasant in that they are not tacky (i.e., they have a silky feel), they have a matte appearance (i.e., not shiny), they are comfortable when applied, and they are easy to apply and remove.

Of particular significance is the fact that the compositions of the present invention can be produced in any form from a liquid to a thick paste and, thus, can be delivered by any conventional means.

The first ingredient of the compositions of the invention are silicone gums. These gums provide the compositions herein with the ability to form substantive, matte films and, conversely, without such gums the compositions of the invention are sticky and easily removed (e.g., washing or smearing). While such gums are typically high molecular weight polydimethylsiloxanes terminated with unreactive groups such as trimethylsiloxy or reactive groups such as dimethylhydroxysiloxy or dimethylvinylsiloxy,



nearly any silicone gum, or mixtures thereof, will function herein. Most preferably, the silicone gum is a dimethylhydroxysiloxy -terminated polydimethylsiloxane.

Silicone gums typically have viscosities up to 50 million mm^2/s at 25^0C and have number average molecular weights (Mn) of up to 700,000 or more. Preferably, the gums have an Mn of about 200,000 to 400,000.

Such gums and methods for their production are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968. In addition, silicone gums are commercially available from, for example, Dow Corning Corporation.

Generally, silicone gums are added to the composition of the invention in amounts of about 1 to 25 wt %. Preferably, silicone gums are used in an amount of about 5 to 15 wt %.

The composition of the invention also contains silicone fluids having viscosities of about 10 to 60,000 mm^2/s at 25^0C. These fluids plasticize the compositions herein and improve their spreadability and conformability. While such fluids are typically linear polydimethylsiloxanes terminated with unreactive groups such as trimethylsiloxy or reactive groups such as dimethylhydroxysiloxy or dimethylvinylsiloxy, nearly any silicone fluid, or mixtures thereof, will function herein. This includes, for example, fluids with small amounts of branching or fluids with organic groups other than methyl attached to silicon.

As noted, the silicone fluids herein will have viscosities of about 10 to 60,000 mm^2/s at 25^0C. Preferably, the silicone fluids will have viscosities of about 20 to 20,000 mm^2/s at 25^0C. Most preferably, the silicone fluid comprises a mixture of silicone fluids having viscosities of about 20 and about 12,500 mm^2/s at 25^0C.

Such fluids and methods for their production are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968. In addition, silicone fluids are commercially available from, for example, Dow Corning Corporation.

Generally, silicone fluids are added to the composition of the invention in amounts of about 1 to 40 wt %. Preferably, silicone fluids are used in an amount of about 20 to 30 wt %.

The composition of the invention also contains silicone waxes. These waxes provide the compositions herein with their silky, non-tacky and semi-occlusive properties. The occlusive property, in turn, provides skin hydration which is a major factor in scar treatment. These waxes also act as a hardening lubricant which causes a reduction in the elastic contribution of the gums under stress and a reduction in the creep of the film. Nearly any silicone wax, or mixtures thereof, will function herein.

Preferred silicone waxes suitable for use in the present invention include alkylmethylsiloxane copolymers having the following formulations:

1. $(RMeSiO)_a(Me_2SiO)_b$

or

2. $R'Me_2(RMeSiO)_y\ (Me_2SiO)_z\ SiMe_2R'$

wherein R is C_nH_{2n+1}, R' is R or Me, Me is CH_3, n is 5 to 45, preferably 10-30, a is an integer from 3 to 10, b is an integer of 0 to 10, a + b is 3 to 10 and y and z are independently 0 or a positive integer of, for example, 1-1000, provided the resultant material is waxy in character, i.e., when R' is Me, y must be 1 or greater.

Preferably, the silicone wax comprises a trimethylsiloxy-terminated poly(dimethyl, methyloctadecyl)siloxane.

The silicone waxes of the present invention typically have melting points of between about 30° C and about 100°C.

Methods for the preparation of such materials are known in the art, and such methods are described in, for example, U.S. Pat. No. 5,017,221 which issued May 21, 1991, and U.S. Pat. No. 5,160,494 which issued Nov. 3, 1992, both of which are incorporated herein by reference. Basically, such methods involve the reaction of a linear siloxane having SiH functionality in the chain with a cyclic siloxane containing Me_2SiO units, and contacting the reaction product with a slight stoichiometric excess of an alkene in the presence of a platinum on carbon catalyst. In addition, silicone waxes are commercially available from, for example, Dow Corning Corporation.

Generally, silicone waxes are added to the composition of the invention in amounts of about 1 to 35 wt %. Preferably, silicone waxes are used in an amount of about 5 to 15 wt %.

The compositions of the invention also contain volatile silicone fluids having viscosities of up to and including about 5 mm^2/s. This volatile fluid allows for easy blending and application of the composition to form a thin film without a cold flow effect. While such fluids are typically cyclic or linear polydimethylsiloxanes or permethylsilanes, nearly any volatile silicone fluid, silane, or mixtures thereof, will function herein.

As noted, the volatile silicone fluids generally have a viscosity of up to and including about 5 mm^2/s, preferably up to about 1.5 mm^2/s at 25° C and more preferably up to about 1.0 mm^2/s at 25° C such that they volatilize in the ambient environment. Generally, such volatile silicone fluids correspond to the average unit formula $(CH_3)_aSiO_{(4-a)/2}$ where *a* has an average value of from 2 to 3. Such

fluids often comprise siloxane units joined by Si-O-Si bonds selected from the group consisting of $(CH_3)_3SiO_{1/2}$ and $(CH_3)_2SiO_{2/2}$units taken in such molar amounts so that there is an average of from approximately two to three methyl groups per silicon in the fluid.

The volatile silicone fluids of the invention can also be a permethylsilane corresponding to the average unit formula $(CH_3)_aSi$ where *a* has an average value of from 2 to 3. Such fluids comprises silane units joined by Si-Si bonds selected from the group consisting of $(CH_3)_3Si$ and $(CH_3)_2Si$ units taken in such molar amounts so that there is an average of from approximately two to three methyl groups per silicon in the fluid.

Preferably the silicone fluid consists essentially of dimethylsiloxane units, and optionally, trimethylsiloxane units. Of particular interest in the present invention are methylsiloxane fluids such as the cyclopolysiloxanes of the general formula $\{(CH_3)_2SiO\}_x$ and linear siloxanes of the general formula $(CH_3)_3SiO\{(CH_3)_2SiO\}_ySi(CH_3)_3$ wherein *x* is an integer of from 3 to 5 and *y* is an integer of from 0 to 4.

Preferred silicone fluids or blends of silicone fluids include cyclic silicones such as hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and the like and linear silicones such as hexamethyldisiloxane, octamethyltrisiloxane, decamethyltetrasiloxane, and the like. The preferred volatile silicone fluid is hexamethyldisiloxane.

These volatile silicone fluids and methods for their manufacture are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968. In addition, these volatile silicone fluids are commercially available from, for example, Dow Corning Corporation.

Generally, the volatile silicone fluids are added to the composition of the invention in amounts of about 1 to 90 wt %, preferably 20 to 90 wt % and more preferably 40 to 70 wt %.

The compositions of the present invention may be prepared by simply mixing the components in any desired order. Apparatuses such as stirrers, blenders, mills and the like, and any other means known in the art can be used. In addition pressure vessels, condensing systems and other means known in the art and commonly used to retain a volatile component in a mixture may be employed in the preparation of the present invention.

By changing the ratio of components in the compositions of the present invention, one has great flexibility in producing compositions with a wide range of physical properties and, thus, a wide range of utilities. For example, compositions from liquids to pastes can be produced and these compositions can be changed to suit the type of scar. Similarly, the compositions may be changed for uses outside scar treatment such as in cosmetics, skin care, pharmaceutical delivery, veterinary applications and the like.

The composition of the invention can optionally comprise other ingredients such as additional diluents, dispersants or carriers, emollients, humectants, thickeners, fillers, preservatives, stabilizers, buffer systems, plant extracts, amino acids, activity enhancers, cosmetic ingredients such as colorants, perfumes, emulsifiers, and sunscreens, essential oils, antiparasitics, repellents and pharmaceutical agents.

The following non-limiting examples are provided so that one skilled in the art can more readily understand the invention.

Example 1

The present example shows the moisture vapor transmission rate for compositions of the present invention and comparative materials.

Composition A was prepared by thoroughly mixing 26.38 g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000; 18.67 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500 mm^2/s; 37.04 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20 mm^2/s and 17.9 g of trimethylsiloxy-terminated poly(dimethyl, methyloctadecyl)siloxane wax having a melting point of 32°C. 43 g of composition A was dispersed into 57 g of hexamethyldisiloxane.

Composition B was prepared by thoroughly mixing 26.2 g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000; 19.2 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500 mm^2/s; 36.8 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20 mm^2/s and 17.8 g of trimethylsiloxy-terminated poly(dimethyl, methyloctadecyl)siloxane wax having a melting point of 32°C. 43 g of composition B was dispersed into 57 g of hexamethyldisiloxane.

A comparative composition C was prepared by thoroughly mixing 26.2 g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000; 19.2 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500 mm^2/s and 36.8 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20 mm^2/s. 43 g of composition C was dispersed into 57 g of hexamethyldisiloxane.

A second comparative composition D comprising lot 1128/107 of the commercial gel Kelocote™ from Allied Biomedical, Paso Robles, CA. .

Each of these materials, compositions A, B, C and D, were tested for moisture vapor transmission rate. The experiment was based on the ASTM E96-95 entitled "Standard Test Methods for Water Transmission of Materials" and conducted according to the following parameters : 1) About 14.5 mg/cm² of tested material was coated with a handcoater onto a 55 mm diameter disc made from a microporous membrane which supports the material during the test. The microporous membrane is a PET membrane with an average pore size of 0.2 µm from 3M™ referenced as 3M™ CoTran 9711 Membrane. 2) Each coated disc was put onto a cylindrical cup (h # 40 mm, Ø # 40 mm) which contains 20 ml of demineralised water. 3) The trials were done in a climatic system at a temperature of 32°C and at 50% relative humidity. The results are shown in Table 1.

Table 1 :

Composition	Coated weight (mg/cm²)	MVTR (g/m².24h)
A	14.9	112.4
B	14.1	109.4
C	13.5	183.5
D	15.9	175.5
blank (membrane CoTran)	0	2625.7

MVTR = Moisture Vapor Transmission Rate

Example 2

The present example shows the oxygen permeability for materials of the present invention and comparative materials.

Composition A and comparative compositions C and D were prepared as in Example 1.

Each of these materials was tested for oxygen permeability. The experiment was based on a chromatographic method as documented in the ISO/CD 15105-2 and conducted according to the following parameters : 1) About 17.2 mg/cm² of tested material was coated with a handcoater onto a 55 mm diameter disc made from a microporous membrane which supports the material during the test. The microporous membrane is a PET membrane with an average pore size of 0.2 µm from 3M™ referenced as 3M™ CoTran 9711 Membrane. 2) Each coated disc was put into the chromatography cell to form a 0.5 cm² interface between a flow of helium as chromatographic carrier gas and a flow of gas at atmospheric pressure containing 50% oxygen. 3) The trials were done at a temperature of 23°C and at 0% relative humidity. The results are shown in Table 2.

Table 2 :

Composition	Coated weight (mg/cm²)	Oxygen gas permeability ($cm^3/m^2.24h.bar$)
A	15.4	52,000
C	19.5	201,600
D	16.8	201,600
blank (membrane CoTran) based on standard NF Q 03076	0	around 10^{10}

Example 3

The present example shows the rheological behaviour for materials of the present invention and comparative materials.

Composition A was made by the process described in Example 1.

Comparative composition E was prepared by thoroughly mixing 262.1 g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000; 192 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500 mm^2/s and 368 g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20 mm^2/s. 43 g of composition E was dispersed into 57 g of hexamethyldisiloxane. A second comparative composition F comprises only dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000.

Each of these materials was tested for its rheological behaviour. The experiment was conducted by recording the elastic and loss moduli of a 0.5 ml sample with a controlled stress rheometer (Carrimed™ CSL 500 from TA Instrument) equipped with a two-parallel plate geometry spaced from 100 µm and the upper plate has a 2 cm diameter. The test conditions were $1.75.10^{-2}$ rad strain for 2 hours under 1 Hz at 25°C. The results are shown in Table 3.

Table 3 :

Composition	G' (Pa)	G'' (Pa)
A	1,700	1,400
E	2,400	1,200
F	22,200	26,400

Claims:

1. A composition suitable for the treatment of scars comprising:
1-25 wt. % of a silicone gum;
1-40 wt. % of a silicone fluid having a viscosity of 10 to 60,000 mm^2/s at 25^0C ;
1-35 wt. % of a silicone wax; and
20-90 wt. % of a volatile permethylsilane or silicone fluid having a viscosity up to and including 5 mm^2/s at 25^0C.

2. The composition according to claim 1 wherein the silicone gum comprises a hydroxyl-terminated polydimethylsiloxane and is present in an amount of 5 to 15 wt %.

3. The composition according to claim 1 wherein the silicone fluid has a viscosity of 20 to 20,000 mm^2/s at 25^0C and is present in an amount of 20-30 wt %.

4. The composition according to claim 3 wherein the silicone fluid comprises a mixture of silicone fluids having a viscosity of about $20mm^2/s$ at 25^0C and 12,500 mm^2/s at 25^0C.

5. The composition according to claim 1 wherein the silicone wax comprises a trimethylsiloxy-terminated dimethyl, methyloctadecylsiloxane and is present in an amount of 5 to 15 wt %.

6. The composition according to claim 1 wherein the volatile permethylsilane or silicone fluid comprises hexamethyldisiloxane and is present in an amount of 40 to 70 wt %.

7. The composition according to claim 1 also comprising a pharmaceutical agent.

8. The composition according to claim 1 also comprising a cosmetic ingredient.

9. The composition according to claim 1 also comprising a veterinary ingredient.

10. A method of forming a film on a substrate comprising:
(A) mixing components comprising:
1-25 wt. % of a silicone gum;
1-40 wt. % of a silicone fluid having a viscosity of 10 to 60,000 mm^2/s at 25°C ;
1-35 wt. % of a silicone wax; and
20-90 wt. % of a volatile permethylsilane or silicone fluid having a viscosity up to and including 5 mm^2/s at 25°C;
(B) applying the mixture formed in (A) to a substrate; and
(C) allowing the volatile permethylsilane or silicone fluid to evaporate and thereby deposit a film on the substrate.

11. The method of claim 10 wherein the substrate is skin.

12. The method of claim 10 wherein the mixture formed in (A) also comprises a pharmaceutical agent.

13. The method of claim 10 wherein the mixture formed in (A) also comprises a cosmetic ingredient.

14. The method of claim 10 wherein the mixture formed in (A) also comprises a veterinary ingredient.

15. A composition substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying examples.

16. A method of forming a film on a substrate substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying examples.

Dated this 23rd day of November, 2004
Shelston IP
Attorneys for: Dow Corning France S.A.