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(54) Title: AN ANTI CHAFING GEL COMPOSITION

(57) Abstract: A gel composition comprising silicone crosspolymer and silicone oil wherein the composition when applied to the skin adheres to the skin with a work of adhesion of more than about 0.500 Newton.sec when measured by TA.XT plus text analyzer using a mucoadhesive rig and forms a film with a coefficient of friction of less than 0.400 when measured by Automatic surface tester (method ASTM D 1894).



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AN ANTI CHAFING GEL COMPOSITION

The present invention relates to gel composition and its use to prevent or treat chaf, razor burns, itching and/or scar rash on a skin surface. The gel composition of the present invention when applied on the skin surface demonstrates excellent anti friction properties and abrasion resistance. The gel of the present invention imparts lubrication to skin surfaces, protects the skin surfaces from irritation, inflammation, chafing and may assist in preventing injury to the skin surfaces, thus avoiding violation or infection of the surfaces.

BACKGROUND OF THE INVENTION

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Skin when exposed to constant friction may become irritated, chaffed and could get injured. This can be a particular problem among many human, whether caused by constant rubbing against another skin surface or by frictional exposure to an external surface such as cloth or solid surfaces depending upon the human's activity.

20

Chafing occurs where parts of the skin such as on the inner thighs, groin areas, armpits, nipples, etc. as a consequence of resistance from body parts rubbing jointly, or resistance from clothing and sweating. Chafing also occurs on the feet due to rubbing and friction with parts of footwear especially if it is new. Chafing mostly occurs around the bra line (in the women), nipples (in the men), inner thighs, groin areas, and under arms. Chafing gets aggravated while undergoing physical activities such as walking, running, swimming, playing sports and other movement oriented activities. Hot and humid climatic conditions and bad lifestyle practices such as wearing synthetic or tight fitting clothes/footwear, overcrowding and excessive travel in congested areas further increases risk for chafing. It is also aggravated due to excess body weight in overweight and obese people, diabetics, people suffering from thyroid and genitourinary disorders and immune compromised people. Causes of chafing are frequent motion -- particularly, skin resistance against movable fabric or other skin.

25

Common symptoms of chafing is painful stinging or burning feeling. Chafing is associated with rash, redness, tearing or scraping of the skin exposing the skin to possible infection. Use of products to soothe skin and alleviate chafing is well known, and there have been a variety of products available on the market to perform the required function such as powders,

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5 petroleum jelly, ointments, oils, lotions, creams and the like. Some of them such as ointments, lotions spread to the clothing and stain it and may later lose their adherence to the skin. Particulate products may not provide to the human protection from chafing due to lower adherence to the skin and results in need for frequent application.

Hence, there is a need for a skin protectant which can cover the surface and forms a film
10 which acts as a protective barrier and reduces the impact of friction to prevent and treat erythema and frictional dermatitis . However, most of the current remedies for chafing need to be applied frequently every couple of hours to maintain and give relief from the pain and irritation on the skin. This can be very inconvenient for patient as they need to frequently go to the rest rooms and apply the topical product, hence there is a need for a product with
15 improved adherence and abrasion resistance resulting in a longer duration of protection.

Chafing is aggravated by sweating and as sweat creates a breeding area for germs such as bacteria and fungus it causes irritation and skin diseases. Further, the germs could enter the body via skin opening due to chafing. In order to avoid this phenomena the anti chafing composition of the present invention may comprise antimicrobial and/or anti-inflammatory
20 agents.

The present invention relates to a gel composition which acts as a skin protectant and prevents or treats symptoms associated with chafing.

25 **RELATED ART**

United States patent publication no. 20060159645 (referred to herein as '645 application; Applicant M/s JOHNSON & JOHNSON) discloses silicone topical compositions for the prevention and/or treatment of chafing. The composition post application to the skin dries
30 to a powder-like consistency. The '645 application does not suggest adhesive and abrasive resistant properties of the composition. The gel composition of the present invention forms a barrier film which lowers the friction on the skin surface post application. Further, it results in a smooth, non-powdery feel with good adhesive and abrasive resistant properties. Further, the composition of the present invention also has a long lasting effect.

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5 **United States Patent No. 8663665** (referred to herein as '665 patent; assigned to M/S Momentive Performance Materials Inc.) teaches an anti-chafing composition comprising an effective amount of boron nitride. The gel composition of the present invention is devoid of boron nitride but still forms a film with low friction which has long lasting effect.

10 **United States Patent No. 9393261** (referred to herein as '261 patent; assigned to M/s Body Glide LLC) discloses an anti-chafing balm comprising chelated silver oxide. The gel composition of the present invention is devoid of the expensive silver oxide.

United States Patent No. 8778406 (referred to herein as '406 patent; assigned to M/s Joyce Labs, LLC) teaches an aerosol composition with zinc oxide which prevents or mitigates irritation on the skin by protecting against or relieving chafing and itching. The gel composition of the present invention is not an aerosol composition and does not contain zinc oxide.

20 **United States Patent No. 6949249** (referred to herein as '249; assigned to M/s JOHNSON & JOHNSON) teaches a spray pumpable liquid composition which has suitable adherence to the skin. The gel composition of the present invention is a gel.

PCT publication WO2017213505 (referred to herein as '505) teaches antichafing spray compositions devoid of silicone elastomer cospolymers. The gel composition of the present invention is a gel comprising silicone elastomer cospolymers.

United States Patent No. 9511034 (referred to herein as '034; assigned to M/S Biosilicote Inc.) teaches a method of treating burns, wounds, scars and keloids. The composition of the present invention prevents chafing and treats the abrasion of the skin surface caused by chafing by application of a single gel composition comprising silicone crosspolymers.

5

OBJECT OF THE INVENTION

The object of the present invention is to provide a gel composition which provides a film with beneficial properties such as low coefficient of friction and adheres to the skin. Further, the film has high abrasion resistance resulting in longer duration of protection for the skin against irritation/injury due to friction.

Another object of the present invention is to provide a gel product as described above which can be applied to the affected area to keep the skin dry and prevent conditions such as Athlete's foot (tinea pedis), Jock Itch (Tinea Cruris), Ringworm (Tinea Corporis), Candidiasis and also prevent diaper rash and chafing commonly occurring in infants and geriatrics who are wearing diapers for long hours per day.

SUMMARY OF THE INVENTION

20 A gel composition comprising

- (a) one or more silicone crosspolymer in about 1 to about 50 %w/w of the composition and silicone oil in about 50 to about 99 %w/w of the composition;
- (b) sweat and/or sebum absorbing agent in about 0.1 to about 25 %w/w of the composition;
- 25 (c) optionally non-volatile film forming polymer in about 0.1 to about 25 %w/w of the composition;
- (d) optionally skin rejuvenating and/or soothing agent in about 0.1 to about 25 %w/w of the composition ;

wherein the composition when applied to the skin adheres to the skin with a work of adhesion of more than about 0.500 Newton.sec when measured by TA.XT plus text analyzer using a mucoadhesive rig and forms a film with a coefficient of friction of less than 0.400 when measured by Automatic surface tester (ASTM D 1894).

5 **DESCRIPTION OF THE INVENTION**

Chafing is a friction-induced injury to the skin, ranging from minor irritation or abrasion where layers of the skin are worn away, or ruptured. Moisture, salts and minerals excreted as perspiration often aggravate, accelerate and exasperate chafing. The effects of chafing are seen, for example, as rash, redness, burning sensation and discomfort during movement..
10 Chafing includes conditions of skin irritation and inflammation namely erythema and frictional dermatitis, leading to a feeling of burning and discomfort on movement. Use of compounds to soothe skin and alleviate chafing is well known, and there have been a variety of products available on the market to perform the required function.

15

Chafing is a simple problem with potentially large impact and chances of infection. It is commonly seen in intimate areas. Majority of fungal and yeast infections such as tinea cruris (jock itch), tinea corporis (ringworm) and candidiasis begin with chafing. Doctors strongly feel the need for an early intervention to prevent chafing.

20

We have surprisingly found a gel composition which on application to the skin imparts dual properties of providing adhesion with a low coefficient of friction. The composition of the present invention has improved abrasion resistance leading to a long lasting action. It also provides a smooth and slippery feel.

25

According to one embodiment of the present invention is a gel composition comprising silicone crosspolymers and silicone oil wherein the composition when applied onto the skin in an effective amount adheres to the skin and forms an antifriction barrier film.

More specifically the gel composition of the present invention is an anti chafing gel composition.

30

The compositions useful in the methods of this invention relate to non-aqueous or anhydrous compositions. The composition of the present invention is preservative, colourant and fragrance free resulting in a hypoallergenic composition.

35

The gel composition of the present invention adheres to the skin and with a work of adhesion of more than 0.500 Newton.sec when measured by TA.XTplus Texture analyzer using a mucoadhesive rig. Preferably, the work of adhesion is more than 0.600 Newton.sec when measured by TA.XTplus Texture analyzer using a mucoadhesive rig. The higher the

5 adhesiveness the better the ability of the composition to adhere to the skin surface to form a protective film.

The gel composition of the present invention exhibits a coefficient of friction below 0.400 when measured by Automatic surface tester (method ASTM D 1894). Preferably, the coefficient of friction is below 0.300 when measured by Automatic surface tester (method
10 ASTM D 1894). A lower coefficient of friction reflects improved anti-friction property of the composition. Lowering of friction on the skin surface helps to reduce the friction which is the cause of chafing, reduces irritation and chafing.

Additionally, the gel composition of the present invention spreads well and provides a
15 smooth and slippery feel as compared to the prior known powdery feel.

We have surprisingly found that marketed products have good adhesion properties and coefficient of friction but unfortunately they do not protect the skin for longer duration as they have poor abrasion resistance.

The gel composition of the present invention when applied onto a substrate in an effective
20 amount also imparts abrasion resistance of at least 10 cycles when measured by abrasion test IS12673-1989 or ASTM D 3885. Preferably, abrasion resistance of at least 12 cycles when measured by abrasion test IS12673-1989 or ASTM D 3885. The higher the number of cycles the better the abrasion resistance and the gel is retained on the skin for a longer time.

Further, the composition of the present invention when applied to the skin surface in an
25 effective amount exhibits a significantly higher ability to be retained on the skin when exposed to forced abrasion using a dry sponge massager and thus providing a longer duration of protection.

The gel composition of the present invention comprises silicone crosspolymers in about 1 to about 50% w/w of the composition. Preferably, silicone crosspolymers in about 1 to about
30 30% w/w of the composition.

The silicone crosspolymer(s) may have an average molecular weight in excess of 10,000 (e.g., between about 10,000 and 10,000,000). Examples of silicone crosspolymers included but not limited to dimethicone/vinyldimethicone crosspolymers, dimethicone crosspolymers, dimethicone/phenyl vinyl dimethicone crosspolymers, vinyl dimethicone/methicone

5 silsesquioxane crosspolymers, dimethicone/PEG-10/15 crosspolymers, PEG-15/Lauryldimethicone crosspolymers and mixtures thereof.

The gel composition of the present invention comprises silicone oils in about 50 to about 99 %w/w of the composition; included but not limited to dimethicone, cyclopentasiloxane, simethicone, methyl dimethicone, methyl trimethicone, phenyl siloxyphenyltrimethicone, trisiloxane and the like. Preferably, silicone oils are in about 70 to about 99 %w/w of the composition

The gel composition may comprise silicone elastomer gels which are blends of silicone crosspolymers and silicone oils.

15 The gel composition of the present invention may also comprise additional excipients such as sweat absorption, sebum absorption, skin rejuvenating, soothing agents, non-volatile film forming polymer ranging from 0.1 to 25%.

The amount of excipients in the gel composition of the present invention may be varied within wide parameters, but should be in a sufficient amount for the composition when applied on the skin to act as an antifriction barrier film on the applied surface of the skin such that the gel suitably adheres to the skin, and in any event, the composition effectively inhibits or reduces irritation or chafing to the skin caused by rubbing, whether skin against skin or against another object including, but not limited to apparel and footwear.

25 The sweat and/or sebum absorbing excipient(s) used in the present invention may be selected from but not limited to silica silylate, magnesium alumina meta silicate, engineered particles of silica, silicic acids and any types of derivatives and modifications thereof. Suitable examples comprise polysilicic acids, silicic anhydride, fumed silica, hydrated silica, silica gel, silicate esters and/or silicate salts such as sodium silicate magnesium silicate, calcium silicate and all types of starch and starch derivatives. The sweat and sebum absorbing excipient(s) may be used in the range 0.1 to 25% by weight of the composition.

30 Preferred range of sweat and/or sebum absorbing excipient(s) when it does not comprise of starch and/or starch derivatives is less than 1.0% by weight of the composition; more preferably about 0.1% to about 0.5% w/w of the composition. The preferred range of sweat and/or sebum absorbing excipient(s) when it comprises of starch and/or starch derivatives is about 0.1 to about 15% w/w of the composition.

5 The non-volatile film forming polymer used in the present invention may be a composition of trimethylsiloxysilicate and the like. The non-volatile film forming polymer may be used in the range of about 0.1 to about 25% w/w of the composition. Preferably, about 0.1 to about 10% w/w of the composition.

10 The skin rejuvenating and/or soothing agent used in the present invention may be selected from curcumin analogs, Balloon Vine extract, Echium Oil, Blackcurrant seed oil, sunflower oil concentrate, tea tree oil, tulsi, neem oil, coconut oil, olive oil and the like. The skin rejuvenating and/or soothing agent may be used in the range about 0.1 to about 25% w/w of the composition. Preferably, about 0.1 to about 10% w/w of the composition.

15 The process used for the preparation of the composition of the present invention entails a cold mixing process without any heat. The crosspolymer gel(s) are mixed in a mixer and the excipients dispersed in cyclopentasiloxane and /or dimethicone are added to the crosspolymer gel(s) and mixed.

20 The gel compositions of the present invention may be packaged in a container that is well known by an artisan of ordinary skill, e.g., low density polyethylene tube or laminated aluminum tubes with a dispensing tip head.

25 According to yet another embodiment of the present invention is a method of preventing or treating symptoms associated with a topical skin disorder in a human patient, the method comprising contacting a skin surface in need of such symptomatic prevention or treatment with the gel composition in an amount and period of time effective to symptomatically prevent or treat the skin disorder or symptoms of the skin disorder.

The skin disorder may be irritation of skin, chafing, razor burn, itching or pruritis, scar rash, diaper rash, athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) and candidiasis by application of gel composition of the present invention.

30 The symptoms associated with the skin disorder may be itching, burning, discomfort, numbness and tingling.

The gel composition of the present invention is applied to the skin one to three times daily. When used in treating chafing of one skin surface against another surface, the composition may be applied until the chafing or irritation is alleviated or it can be used prophylactically on a chronic basis. More preferably, the composition useful in the methods of this invention is applied to two or more surfaces that may come into contact with each other. The skin

5 surfaces which come into contact with each other are the chafing prone areas and by application of the gel of the present invention the probability of chafing is reduced.

The human may also, in accordance with the methods of this invention, apply such compositions to his or her skin which may come into frequent contact with external clothing or shoes, in order to protect such skin from chafing, irritation and or blistering.

10

Definition of terms

As used herein, the term "anti-chafing composition" means any topically applied composition
15 comprising ingredients capable of reducing, relieving, or minimizing chafing from friction of human skin, particularly friction induced injury to the skin ranging from minor irritation or abrasion, resulting from the rubbing of skin against skin, clothing, shoes, or other materials. Chafing includes conditions of skin irritation and inflammation namely erythema and frictional dermatitis

20

As used herein, the term "Abrasion resistance" means a property which allows a material to resist wearing off due to repetitive rubbing. The composition is expected to be retained on the skin for a longer time when it has a higher resistance to abrasion.

As used herein the term "Adhesiveness or Adhesive" is the force that resists the separation
25 of two bodies in contact. The composition is expected to adhere to the skin when it has a higher work of adhesion.

As used herein, the term "Coefficient of Friction" means a value that shows the relationship
30 between the force of friction between two objects and the normal force between the objects. It is the ratio of the force of friction between an object and a surface to the frictional force resisting the motion of the object.

5 As used herein the term “applied on to the skin in an effective amount” means the anti chafing composition being applied in an amount sufficient to cover the affected area of the skin.

As used herein the term “silicone elastomer gel” means a silicon crosspolymer blended with silicone oils.

10

The following examples illustrate preferred embodiments in accordance with the present invention without limiting the scope of the invention

15

20

25

5 **EXAMPLES****Example 1: Compositions of the invention**

Excipients	%w/w						
	1a	1b	1c	1d	1e	1f	1g
Dimethicone/VinylDimethicone Crosspolymer	5.7	6.4	6.4	6.1	3.6	-	-
Dimethicone crosspolymer	1.4	-	-	-	4.5	8.7	6.9
Cyclopentasiloxane	81.1	90.5	90.4	89.2	75.9	75.3	77.1
Dimethicone	8.6	-	-	-	12.9	12.9	12.9
Corn starch	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Silica Silylate	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Magnesium alumina metasilicate	0.1		0.1	0.1	-	-	-
Trimethyl siloxy silicate	-	-	-	1.5	-	-	-
Total	100	100	100	100	100	100	100

The above examples were prepared by a cold mixing process without using any heat. The crosspolymer gels were mixed in a mixer. Corn starch, silicates were dispersed in cyclopentasiloxane/dimethicone and added to the gel mass. Other excipients were added and mixed.

The examples of the above compositions were tested for adhesiveness, coefficient of friction and resistance to abrasion.

15

The examples were tested for their adhesiveness to confirm that the protective barrier film of the invention would adhere to the skin and ensure the required effect. Adhesiveness test was carried out for the above mentioned compositions and the test parameters were as follows :

20 Instrument used : TA.XT.plus Texture analyzer.
 Probe: Mucoadhesion rig
 Test Mode: Tension Pre-Test Speed: 0.50 mm/sec.
 Test Speed: 0.10 mm/sec
 Post-Test Speed: 0.10 mm/sec
 25 Applied Force: 5.0 g
 Return Distance: 15.0 mm

5 Contact time: 60 sec

Procedure:

Apply 200 µl of the sample on the sampling slot, measure the adhesiveness using the above parameters. Sample of a similar marketed product (Reflesport – marketed by Reckitt Benkiser) was also tested for adhesiveness. Sodium CMC gels were also prepared and tested as positive control and cyclopentasiloxane was tested as a negative control.

10

Test ID	Work of Adhesion (Adhesiveness)	Test ID	Work of Adhesion (Adhesiveness)
	N.sec		N.sec
Positive Control		Negative control	
Sodium CMC 3% gel	0.460	Cyclopentasiloxane	0.090
Sodium CMC 4% gel	0.792		
Test products			
Example 1a	0.707	Reflesport	0.825
Example 1b	0.827		
Example 1c	0.734		
Example 1d	0.593		
Example 1e	0.690		
Example 1f	0.716		
Example 1g	0.482		

Sodium CMC gels are reported in literature to have good adhesive properties and so the adhesive values of 3% and 4% gels could be considered as those desirable in the invention. The adhesiveness value of marketed product Reflesport was found to be good.

15

The coefficient of friction of the above examples was tested to understand the ability of the composition to reduce the friction on the surface on the substrate when applied.

The coefficient of friction was tested on the following equipment using parameters as listed below

20

Instrument Name: Automatic Surface Tester
 Model / Product No. : KES FB4- AUTO-A
 Make: KES KATO TECH CO. LTD. Japan.
 Method : Kawabata method (ASTM D 1894)

25

The samples (1gm) were applied on a substrate of 20 x 20 cms size substrate and dried. The coefficient of friction was measured in the standard mode using 200gms as the force applied and a friction contactor size of 10 x 10 mm.

S No	Example	Coefficient of friction (MIU)
1	Example 1a	0.160
2	Example 1c	0.168
3	Example 1f	0.166
4	Reflesport	0.172

5

The above results confirm that the surface of the substrate after application of the compositions of the inventions demonstrate the ability to reduce the friction of the surface by more than 80% as all the values of the coefficient of friction are below 0.200 MIU.

10 The examples were also tested for resistance to accelerated abrasion to help understand the strength of the protective film to withstand rubbing off and give a longer duration of protection.

The abrasion resistance test was conducted using the following equipment and parameters

Standard Test Method No. customized based on ASTM D 3885/IS 12673-1989

Type of Abradant used : Zero Emery Paper

15 Type of Abrasion : Unidirectional

Instrument Name: Universal Wear Tester

Model / Product No. : M282

Make: SDL ATLAS, HONG KONG

-Air Pressure Used: 4 psi

20 -Load Used: 0.5 lb

-Mode: Unidirectional

-Stroke Length: 1 inch

25 The samples of the above example were mixed with a colourant and applied as a uniform layer on the substrate fabric. The films were dried and then subjected to abrasion on the equipment measured as number of cycles required to remove the coloured film.

The cycles required to peel off the film for the examples was as given below. A sample of the marketed product with a similar composition (Reflesport – marketed by Reckitt benkiser) was also tested for comparison

30

S No	Example	Observation (No of cycle/s to peel off)
1	Example 1a	50
2	Example 1c	15
4	Reflesport	05

35 1a and 1c showed very good adhesive values (above 0.700 N.sec) and abrasion resistance of more than 10 cycles.

5 **Example 2: Compositions of the invention**

Excipients	%w/w						
	2a	2b	2c	2d	2e	2f	2g
Dimethicone/VinylDimethicone Cross polymer	6.0	5.4	5.6	6.0	5.8	5.7	5.2
Dimethicone crosspolymer	-	2.1	1.4	0.7	0.7	0.7	2.1
Cyclopentasiloxane	89.0	76.5	81.2	85.8	85.2	84.6	76.6
Dimethicone	-	12.9	8.6	4.3	4.3	4.3	12.9
Corn starch	5.0	3.0	3.0	3.0	3.0	3.0	3.0
Silica Silylate	-	0.1	0.1	0.1	0.1	0.1	0.1
Magnesium alumina metasilicate	-		0.1	0.1	0.1	0.1	0.1
Trimethyl siloxy silicate					0.75	1.5	
Total	100	100	100	100	100	100	100

The above examples were all prepared using the cold mixing process as explained in example 1.

10 The compositions were tested for adhesiveness, coefficient of friction and resistance to abrasion

Example No	Work of Adhesion N.sec	Coefficient of Friction MIU	Resistance to abrasion in no of cycles to peel off
Example 2a	0.809	-	-
Example 2 b	0.762	-	-
Example 2 c	0.696	-	60
Example 2 d	0.671	0.252	60
Example 2 e	0.646	-	45
Example 2 f	0.637	-	60
Example 2 g	0.701	0.222	30

15 The examples demonstrated good adhesiveness properties along with a low coefficient of friction. Further, many of them exhibit a significantly a very good resistance to abrasion as compared to the marketed sample. Thus, the inventive composition has a longer retention on the skin and expected to have a longer duration of anti friction action when applied to the skin.

5 **Example 3 : Compositions of the invention**

Excipients	%w/w							
	3a	3b	3c	3d	3e	3f	3g	3h
Dimethicone/VinylDimethicone Cross polymer	5.3	5.8	5.6	5.6	7.2	5.3	5.7	5.6
Dimethicone crosspolymer	0.8	0.7	0.7	0.7	-	0.8	1.4	0.7
Cyclopentasiloxane	83.5	83.5	81.4	81.4	85.9	78.5	81.0	81.9
Dimethicone	5.2	4.3	4.3	4.3	3.8	5.2	8.6	4.3
Corn starch	5.0	5.0	7.0	7.0	3.0	5.0	3.0	7.0
Silica Silylate	0.1	0.5	1.0	-	0.1	0.1	0.1	0.5
Magnesium alumina metasilicate	0.2	0.25	-	1.0	0.1	0.2	0.2	-
Black currant seed oil, balloon vine extract, sunflower oil concentrate in Octyldodecanol	-	-	-	-	-	5.0	-	-
Total	100	100	100	100	100	100	100	100

The above examples were all prepared using the cold mixing process as explained in example 1.

The compositions were tested for adhesiveness, coefficient of friction and resistance to abrasion

<u>Example No</u>	<u>Work of Adhesion N.sec</u>	<u>Coefficient of Friction MIU</u>	<u>Resistance to abrasion in no of cycles to peel off</u>
Example 3 a	0.646	0.272	14
Example 3 b	0.638	-	-
Example 3 c	0.186	-	-
Example 3 d	0.680	-	-
Example 3 e	0.732	-	-
Example 3 f	0.837	-	-
Example 3g	0.695	0.260	13
Example 3h	0.555	-	-

15

5 **Example 4 : Exemplary Compositions of the invention**

Ingredient	Function	Optional / Required
Dimethicone/VinylDimethicone Cross polymer	Film forming agent, thickener and Gel forming agent	Required
Dimethicone crosspolymer	Film forming agent, thickener and Gel forming agent	Required
Phenyl vinyl Dimethicone crosspolymers	Film forming agent, thickener and Gel forming agent	Required
Vinyl dimethicone/Methiconesilsesquioxane crosspolymer	Film forming agent, thickener and Gel forming agent	Required
Dimethicone/PEG-10/15 crosspolymer	Film forming agent, thickener and Gel forming agent	Required
PEG-15/lauryl dimethicone crosspolymer	Film forming agent, thickener and Gel forming agent	Required
Cyclopentasiloxane	Base Vehicle – Silicone oil/fluid	Required
Trisiloxane	Base Vehicle – Silicone Oil/fluid	
Methyl Trimethicone	Base Vehicle – Silicone Oil/fluid	Required
Diphenyl siloxy phenyl Trimethicone and / or phenyl silicone oils	Base Vehicle – Silicone Oil/fluid	Required
Dimethicone	Base Vehicle - Silicone oil/fluid	Required
Corn starch	Sebum and Sweat absorbent	Required
Silica Silylate	Sebum and Sweat absorbent	Required
Silicate Esters	Sebum and Sweat absorbent	Required
Silicate Salts	Sebum and Sweat absorbent	Required
Sodium silicate	Sebum and Sweat absorbent	Required
Calcium Silicate	Sebum and Sweat absorbent	Required
Magnesium alumina metasilicate	Sebum and Sweat absorbent	Required
Polysilicic Acid	Sebum and Sweat absorbent	Required
Fumed Silica	Sebum and Sweat absorbent	Required
Hydrated Silica	Sebum and Sweat absorbent	Required
Silicic Anhydride	Sebum and Sweat absorbent	Required
Trimethyl siloxysilicate	Film forming agent	Optional
Curcumin Analogues	Skin rejuvenating and soothing agent	Optional
Balloon vine extract	Skin soothing agent	Optional
Echium Oil	Skin soothing agent	Optional
Black Current Seed oil	Skin soothing agent	Optional
Sun flower Oil Concentrate	Skin rejuvenating oil and soothing agent	Optional
Tea tree oil	Skin soothing agent	Optional
Tulsi oil	Skin rejuvenating oil and soothing	Optional

	agent	
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5 **Example 5 :Abrasion Resistance Study on human panel :**

Abrasion Resistance study on Human panel:

Resistance to Accelerated/forced Abrasion study on human panel;

Study Plan: 6 healthy male participants and 6 healthy female participants were selected. The study was a single blind crossover clinical study, in which participants were subjected to test and marketed product simultaneously one on each arm.

10 Gel A is the test product (composition of Example 3g) and Gel B is marketed product (Refle sport)

Procedure and Protocol:

15 A fixed and known amount of gel *i.e.* 0.1 gm was applied of the test and marketed product on a 4cm diameter patch on the fore arm of the participants (the final concentration being 7.96 mg/cm²) and allowed to air dry. Individual formulations namely Gel A (Test product) and Gel B (marketed product) were applied on any of the arm (right/left) based on pre-decided coding system. After the patch was completely dry, sponge massager was used for abrading the patch in clockwise circular motion. The process was repeated at specific intervals until the film fades away.

Observations:

- Gel A and gel B both had the same transparent appearance
- Upon application both gel A and gel B had the same viscous texture and were easy to apply, formed a smooth, silky, non powdery, matt like film which easily air dried in 30 mins.
- Gel A was found to have higher retention on the skin as compared to Gel B when exposed to forced abrasion using a dry sponge massager. The number of cycles required to peel off the gel film was measured for each volunteer.

30 **Mean, SEM and SD of the number of cycles required for abrasion in all the study participants (06 males and 06 females)**

Sr. No.	Gel A Cycles	Gel B Cycles
1	75	35
2	60	50
3	50	35
4	100	50
5	60	35
6	125	85
7	100	75
8	115	100
9	135	70
10	150	100
11	130	100
12	225	200
Mean	110.4	77.9
SEM (Standard Error of	31.9	22.5

Mean)		
SD (Standard Deviation)	48.7	46.3

5 The results obtained from the clinical trial were subjected to two tailed ‘Paired t Test’ using Graph Pad Prism Software. Figure 1 depicts the graph obtained applying Statistics using number of cycles as the variable

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• **Tabular results:**

Table Analyzed	Paired t test data
Column A	Gel A
vs	vs
Column B	Gel B
Paired t test	
P value	P<0.0001
P value summary	***
Are means signif. different? (P < 0.05)	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=6.734 df=11
Number of pairs	12

Discussions and Conclusion:

15 The study was based on comparison between two gels on same person hence two-tailed paired t test was applied to the data. Probability (P) of less than 0.05 is significant *i.e.* confidence interval is ~ 95% when evaluated for cycles need to peel off the film. In this case P is 0.0001 for cycles need to peel off, hence it is statistically significant. This proves that Gel A takes higher resistance time and cycles to get removed from skin.

20 In the present invention we have made use of an accelerated abrasion test as a surrogate measurement to estimate the residence time on the skin when used by consumers in real life situation. Thus according to the data obtained, abrasion resistance of anti-chafe product (Gel A) of example 3g has a significantly longer residence time on skin after application when compared with the marketed product - Reflesport (Gel B).

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5 Claims

1. A gel composition comprising

(a) one or more silicone crosspolymer in about 1 to about 50 %w/w of the composition and silicone oil in about 50 to about 99 %w/w of the composition;

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(b) sweat and/or sebum absorbing agent in about 0.1 to about 25 %w/w of the composition;

(c) optionally non-volatile film forming polymer in about 0.1 to about 25 %w/w of the composition;

(d) optionally skin rejuvenating and/or soothing agent in about 0.1 to about 25 %w/w of the composition ;

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wherein the composition when applied to the skin adheres to the skin with a work of adhesion of more than about 0.500 Newton.sec when measured by TA.XT plus text analyzer using a mucoadhesive rig and forms a film with a coefficient of friction of less than 0.400 when measured by Automatic surface tester (method ASTM D 1894).

2. A gel composition as claimed in claim 1 wherein the composition is an anti-chafing gel composition.

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3. A gel composition as claimed in claim 1 wherein the composition when applied to the skin adheres to the skin with a work of adhesion of more than about 0.600 Newton.sec when measured by TA.XT plus text analyzer using a mucoadhesive rig.

4. A gel composition as claimed in claim 1 wherein the composition when applied to the skin forms a film with a coefficient of friction of less than 0.300 when measured by Automatic surface tester (method ASTM D 1894).

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5. A gel composition as claimed in claim 1 wherein the composition when applied onto the skin forms an abrasion resistant film with abrasion resistance of at least 10 cycles as measured by abrasion test IS12673-1989 or ASTM D 3885.

30

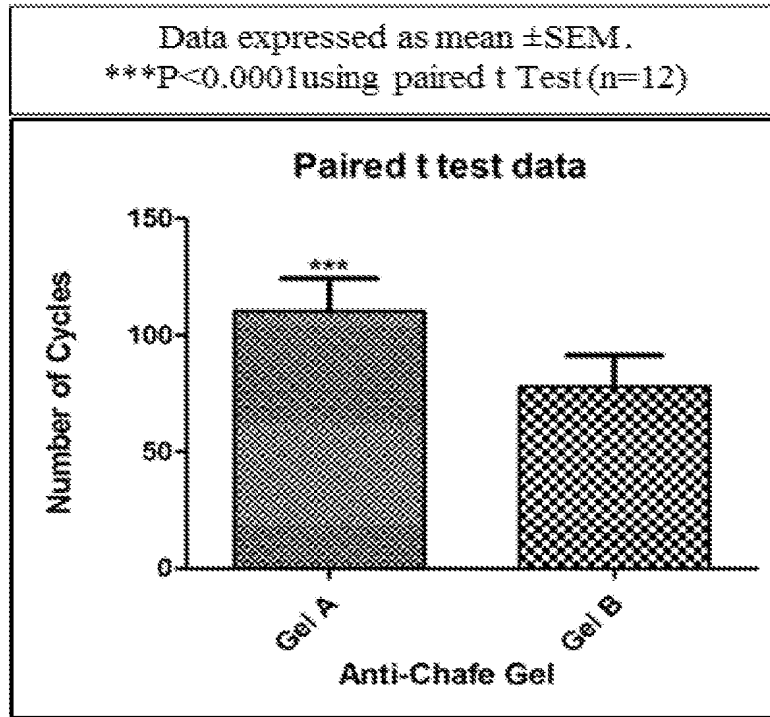
6. A gel composition as claimed in claim 5 wherein the composition when applied onto the skin forms an abrasion resistant film with abrasion resistance of at least 12 cycles as measured by abrasion test IS12673-1989 or ASTM D 3885.

- 5 7. A gel composition as claimed in claim 1 wherein the silicone crosspolymer is selected from dimethicone/vinyldimethicone crosspolymers, dimethicone crosspolymers, phenyl vinyldimethicone crosspolymers, dimethicone/phenylvinyl dimethicone crosspolymers, vinyldimethicone/methicone silsesquioxane crosspolymers, dimethicone/PEG-10/15 crosspolymers, PEG-15/Lauryldimethicone crosspolymers and mixtures thereof.
- 10 8. A gel composition as claimed in claim 1 wherein the silicone crosspolymer is about 1 to about 30 %w/w of the composition.
9. A gel composition as claimed in claim 1 wherein the silicone oil is selected from dimethicone, cyclopentasiloxane, simethicone, methyl dimethicone, methyl trimethicone, phenyl siloxyphenyltrimethicone and trisiloxane.
- 15 10. A gel composition as claimed in claim 1 wherein the silicone oil is about 70 to about 99 %w/w of the composition.
11. A gel composition as claimed in claim 1 wherein the sweat and/or sebum absorbing agent is selected from silica silylate, magnesium alumina meta silicate, engineered particles of silica such as silicic acids, polysilicic acids, silicic anhydride, fumed silica, hydrated silica, silica gel, silicate esters and/or silicate salts such as sodium silicate, magnesium silicate, calcium silicate and all types of starch and starch derivatives.
- 20 12. A gel composition as claimed in claim 1 with a proviso that the sweat and/or sebum absorbing agent is not starch and/or starch derivaives, the sweat and/or sebum absorbing agent is about 0.1 to about 0.5 %w/w of the composition.
- 25 13. A gel composition as claimed in claim 1 wherein when the sweat and/or sebum absorbing agent comprises of starch and/or starch derivatives, the sweat and/or sebum absorbing agent about 0.1 to about 15 %w/w of the composition.
14. A gel composition as claimed in claim 1 wherein the non-volatile film forming polymer is trimethylsiloxysilicate.
- 30 15. A gel composition as claimed in claim 1 wherein the non-volatile film forming polymer is about 0.1 to about 10 %w/w of the composition.

- 5 16. A gel composition as claimed in claim 1 wherein skin rejuvenating and/or soothing agent is selected from curcumin analogs, Balloon Vine extract, Echium Oil, Blackcurrant seed oil, sunflower oil concentrate, tea tree oil, tulsi, neem oil, coconut oil and olive oil.
- 10 17. A gel composition as claimed in claim 1 wherein skin rejuvenating and/or soothing agent is about 0.1 to about 10 %w/w of the composition.
- 15 18. A method of preventing or treating symptoms associated with a topical skin disorder in a human patient, the method comprising contacting a skin surface in need of such symptomatic prevention or treatment with the gel composition of any one of claims 1 to 17 in an amount and period of time effective to symptomatically prevent or treat the skin disorder or symptoms of the skin disorder.
- 20 19. A method as claimed in claim 18 wherein the topical skin disorder comprises at least one of irritation of the skin, chafing, razor burn, itching or pruritis, scar rash, diaper rash, athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) and candidiasis.
- 25 20. A method as claimed in claim 18 wherein the symptoms associated with the skin disorder comprise at least one of itching, burning, discomfort, numbness and tingling.
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Figure 1: Two tailed 'Paired t Test' of clinical trials in Example 3

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INTERNATIONAL SEARCH REPORT

International application No.

PCT / IN 2018/050463

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61K 8/891 (2006.01); A61K 8/895 (2006.01); A61K 8/04 (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPODOC		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016052571 A1 (KOBAYASHI PHARMA CO LTD) 07 April 2016 (07.04.2016) abstract (WPI); claims 1,2,4,5,7 as well as online-translation (EPO): page 5, paragraph 2-page 7, paragraph 5; page 8, paragraph 2; page 9, paragraph 1; page 12, paragraph 3	1,7-17,19
X	EP 3143984 A1 (Shiseido Company Ltd) 22 March 2017 (22.03.2017) paragraphs [0019]-[0020],[0028],[0031]-[0038],[0044]-[0048]; claim 1	1,7-12,16,17
X	WO 2017003139 A1 (AMOREPACIFIC CORPORATION) 05 January 2017 (05.01.2017) abstract; online-translation (EPO): page 2, paragraph 10-page 4, paragraph 7; claims	1,7-11
X	EP 3072915 A1 (SHIN-ETSU CHEMICAL CO., LTD) 28 September 2016 (28.09.2016) paragraphs [0060]-[0062],[0067],[0070],[0074],[0077],[0083],[0087],[0090]; claims 1,5,7	1,7-17
E	WO 2018143061 A1 (SHINETSU CHEMICAL CO) 09 August 2018 (09.08.2018) online-translation (EPO); paragraphs [0011]-[0025],	1,7-10,14,15
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be of particular relevance		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date		"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means		"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 06 November 2018 (06.11.2018)		Date of mailing of the international search report 16 November 2018 (16.11.2018)
Name and mailing address of the ISA/AT Austrian Patent Office Dresdner Straße 87, A-1200 Vienna Facsimile No. +43 / 1 / 534 24-535		Authorized officer KRENN M. Telephone No. +43 / 1 / 534 24-435

INTERNATIONAL SEARCH REPORT

International application No.

PCT / IN 2018/050463

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 19.

because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 19 refers to a method of treatment of the human body, a search has been carried out and is based on the alleged effects of the composition.

2. Claims Nos.: 2 - 6, 18, 20.

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 2-6 lack a technical disclosure. Claim 2 only describes an effect and claims 3-6 refer to properties of the gel after application to the skin. However, only a description of the composition by those components causing said properties/effects is appropriate. Claims 18 and 20 also refer to a method of treatment. As however said claims do not disclose concrete indications, no search has been carried out for said claims.

3. Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT / IN 2018/050463

Patent document cited in search report			Patent family member(s)			Publication date
WO	A1	2016052571	WO	A1	2016052571	2016-04-07
			JP	A	2016069337	2016-05-09
EP	A1	3143984	EP	A1	3143984	2017-03-22
			JP	A	2015218113	2015-12-07
			WO	A1	2015174241	2015-11-19
			TW	A	201545768	2015-12-16
			KR	A	20160139042	2016-12-06
			US	A1	2017266082	2017-09-21
			KR	A	20170122291	2017-11-03
CN	A	106456510	2017-02-22			
WO	A1	2017003139	KR	A	20170003291	2017-01-09
			WO	A1	2017003139	2017-01-05
			TW	A	201707681	2017-03-01
			CN	A	107979997	2018-05-01
EP	A1	3072915	KR	A	20160110125	2016-09-21
			US	A1	2016262991	2016-09-15
			EP	A1	3072915	2016-09-28
			JP	A	2016169324	2016-09-23
			CN	A	105963159	2016-09-28
WO	A1	2018143061	WO	A1	2018143061	2018-08-09