Silicone Film-Forming Technologies
for Health Care Applications

Paal Klykken
Margaret Servinski
Xavier Thomas
Amid continuing industry growth and change, silicones have provided versatile and innovative solutions in the health care market for more than 50 years. As the market evolves and becomes more complex, such as with the introduction of cosmeceutical products, new needs and trends have appeared, and applications for silicones continue to expand. Many owe their origin to the distinctive properties of silicones, including their ability to act as film formers and delivery systems for active ingredients.

Based on their chemistry, silicones can offer a variety of film-forming characteristics, ranging from transient films and thin, superficial coverings to more substantive, longer-lasting films with self-leveling and adhesive properties. This article describes various silicone families and the relationship of their properties to film forming, particularly in emerging wound care applications. Two key features of silicone film-forming properties are described: silicone substantivity on skin and its resulting durability as a film, and the permeability of silicone to many molecules, especially water vapor, oxygen and numerous drugs. Silicone technologies not only provide distinctive properties for innovative health care applications, but they offer enhancements in product aesthetics that can lead to improved comfort for patients and better patient compliance.

A number of developments in the health care and personal care industries have benefited from crossover, synergistic and parallel technology development. Both industries rely on silicone biocompatibility and film-forming properties.

When evaluating silicones for use in film-forming applications, several properties are considered: the biocompatibility of these materials, their mechanical properties, drying and curing time, adhesion to the desired substrate, stability, permeability, hydrophobicity, overall appearance and low shrinkage characteristics. These properties form the foundation for a range of potential health care and personal care applications:

- **Skin Care.** Cosmetic creams, ointments and masks are used in anti-aging applications. They provide benefits including emolliency and moisturization. These silicone-based formulations also are capable of delivering a variety of actives for skin care applications.

- **Wound Care.** Building on the skin care foundation, wound care becomes a logical extension to exploit the film-forming attributes of silicones for compromised skin. Historically, the focus centered on skin barrier applications, including skin sealants. More recent applications include liquid bandages and delivery systems for active ingredients, such as enzymes for debridement of necrotic tissues (1) or silver-based products for wound cleansing.

- **Topical Drug Delivery.** Therapeutic molecules can also be delivered from film formers for the localized treatment of skin and its underlying tissues. Well-known uses include pain relief, anesthetic, antimicrobial and anti-inflammatory applications.

Products of this type might be packaged and delivered in a variety of ways, such as single-use sachets or tubes (for creams, ointments, gel samples), bottle-and brush combinations (e.g., for liquid bandages), sprays or pressurized containers. In addition, the market for wet wipe products continues to grow, and ongoing studies suggest application of various skin barrier films as a means of delivering active ingredients (2).

### Silicone Properties and Families

The ability of various silicones to form films is related to their molecular structure, which is based on a silicon and oxygen backbone to which methyl pendants are attached. Figure 1 shows the basic structure for polydimethylsiloxane (PDMS).

PDMS has a unique configuration, with the nonpolar organic methyl groups forming a “cloud” that surrounds the highly flexible inorganic siloxane backbone. The resulting materials are hydrophobic liquids at room temperature with very low glass transition temperatures (Tg) and high permeability to gas, including water vapor.

Silicones also have low surface tension, which is of primary importance to their spreading properties and film-forming ability. The critical surface tension of PDMS is 24 mN/m, which is greater than the liquid surface tension of 20.4 mN/m at 20°C. In comparison, the critical surface tension of mineral oil and deionized water are 30.4 mN/m at 25°C and 72.0 mN/m, respectively. As a result, PDMS not only spreads easily but can wet almost all surfaces. The surface activity of organosilicones has been thoroughly and extensively studied (3,4).

PDMS forms thin films over skin and other organic substrates and is able to spread over its own absorbed film. Its spreading characteristics can be controlled or fine-tuned by modifying the chemical structure of the material or the composition of formulations into which it is incorporated. These characteristics of easy spreading translate to an ability to aid spreading of other formulation ingredients, such as those in skin creams, lotions or topical drug formulations.

Due to its hydrophobicity, low surface tension and spreading properties, PDMS (specifically, dimethicone) is recognized by the U.S. Food and Drug Administration as a protective agent in topical skin care products (5). The recently finalized FDA skin protectant monograph describes materials used as over-the-counter protectants against conditions that include minor cuts, scrapes, burns, and chapped skin. In practical terms, this means the silicone is considered a safe and effective barrier for skin protection. A barrier of this type would also be considered to minimize infection as well as lessen the likelihood of exposing wound exudate or transferring infection. In addition, the skin protectant monograph allows dimethicone to be claimed as an active ingredient when incorporated into OTC products at concentrations of 1 to 30%.

Some of the first personal care applications for silicone were an ointment containing 30% PDMS (6) and a cosmetically acceptable lotion containing 1.5% PDMS (7). These formulations were evaluated for their protective qualities and ability to aid healing of a variety of dermatologic conditions. More recently, skin barriers for periwound protection contain up to 10% dimethicone to take advantage of this benefit.

Excluding the lowest molecular weight species, silicones remain on the stratum corneum and are not absorbed into lower layers of the skin. Thus, they are particularly suitable for topical applications from a safety perspective. In part due to its long history of use, PDMS is one of the most extensively tested materials for topical personal care and health care applications.

In addition to their film-forming properties, some silicone materials also show an ability to gently adhere to proteinaceous substrates such as skin or hair. Based on alterations to their chemistry, PDMS-based materials may also form substantive, cross-linked films that exhibit wash-off resistance (8).
The properties of basic PDMS materials can be changed by replacing some methyl groups with other organic groups or atoms (e.g., hydrogen, hydroxyl, vinyl, polyethylene oxide, alkoxi, or fluoro alkyl groups). Substitutions of this type can be useful when specific chemical and physical properties are desired, such as adhesion to a certain substrate, higher or lower polarity, better thermostability, enhanced hydrophilicity, compatibility with other organic materials or targeted reactivity. This capability to functionalize PDMS is critical for transforming liquid or highly flowable materials into thermoplastic or thermostet materials such as viscoelastic silicone pressure sensitive adhesives (PSAs) or silicone rubbers, respectively.

Film formers are presented in this article based on their film-forming capability and their basic silicone type as well as their potential durability in terms of film substantivity for health care applications. A variety of silicone families with potential film-forming applications are based on the PDMS structure, including:

- **Silicone fluids (from 0.65 mPa.s to a few thousand mPa.s viscosity).** These materials provide spreading benefits and relatively transient substantivity. They are primarily used as carriers and diluents.

- **Medium to high molecular weight PDMS and its emulsions (from 12,500 mPa.s fluid to silicone gums).** The higher viscosity and also the molecular entanglements (e.g., gum) induced by the increased molecular weight benefit the substantivity of silicone fluids on skin.

- **Silicone compounds (silica or silicate resin in silicone fluids).** The effect of additional substantivity can be obtained by reinforcing or physically cross-linking silicone fluids through silica or resin filler.

- **Dimethicone crosspolymer (swollen and partially cross-linked elastomers).** Additional substantivity is obtained by slightly cross-linking silicone fluids. These materials are currently commercialized as “silicone elastomers” for use in both personal care formulations and topical drug delivery forms.

- **Organofunctional silicones (alkylmethylosiloxane waxes, silicone polyethers).** These copolymers provide complementary properties such as higher occlusivity or greater hydrophilicity to the film former formulations.

- **Pressure sensitive silicone adhesives (PSAs).** PSAs are highly resin-reinforced siloxane networks that allow for prolonged adhesion to skin.

- **In situ cured elastomer films.** These films combine the spreading qualities of silicone fluids, the substantivity of reinforced siloxane networks, and the cohesiveness and elasticity of silicone rubbers.

- **Silicone-organic combinations.** Like simple blends, hybrid networks or copolymers, combinations of silicone and organic technologies can offer the desired characteristics of both (e.g., silicone polyamide, silicone-acrylic hybrids, silicone-plasticized nitrocellulose, silicone-based polyurethane).

The film-forming abilities of a particular silicone material are dependent on the molecular weight, structure and functionality of the polymer. Substantivity and durability of the film vary with the properties of the siloxane and the formulation, with hydrophobic films being water repellent, and as a result, more resistant to wash-off. Figure 2 illustrates the increasing durability of silicones based on their use in film-forming applications for health care.

Table 1 summarizes some of the properties of fluids, PSAs and elastomers.

### Silicone Fluids and Compounds: Transient to Moderate Durability

Transient to medium-term durability, exhibited by the ability of a silicone to form and retain a film structure for several hours after being delivered to the skin, can be achieved in several ways: through volatile (linear and cyclic) silicones, low to high molecular weight PDMS, and silicone com-
Fluids, High Molecular Weight PDMS and Compounds. Silicone fluids and compounds are among the more structurally basic film-forming silicones. In general, the primarily linear (e.g., Dow Corning® Q7-9180 Silicone Fluid and Dow Corning® Q7-9120 Silicone Fluid) or cyclic silicone materials of this group (e.g., Dow Corning® ST-Cyclomethicone 5-NF and Dow Corning® ST-Cyclomethicone 56-NF) form films on the skin, lasting anywhere from a few minutes (in the case of hexamethyldisiloxane 0.65 cSt) to several hours for silicone gumin-fluid materials (such as Dow Corning® Silmogen Carrier or Dow Corning® Dimethiconol Blend 20). High volatility and low viscosity forms of these materials are typically used as solvents and carriers for active ingredients. Basic PDMS materials can be modified chemically to form films with optimized properties adapted to the type of protection needed.

Preliminary studies have documented the utility of the transient film-forming and solvent properties of cyclopentasiloxane (2, 9). Either alone or blended with silicone emulsifiers, cyclopentasiloxane can be useful in removing residual adhesive from first aid bandages and leave a protective film made of higher viscosity PDMS.

Volatile silicones such as cyclopentasiloxane or hexamethyldisiloxane are also ideal delivery vehicles for active ingredients. Cyclomethicones have a long history of use in stick antiperspirants where they act as carriers for antiperspirant salts. They are currently referenced in the USP-27 NF-22. These materials evaporate without a cooling effect like that of alcohol and without leaving a tacky or greasy feel. This successful application suggests a variety of opportunities for the delivery of pharmaceutical actives from topical formulations. For example, a recent patent (10) describes cosmetic or therapeutic aerosol compositions in which the active material is combined with a hexamethyldisiloxane carrier. Such a composition typically contains 75-95% by weight hexamethyldisiloxane, 0.01-15% therapeutic or cosmetic agent, 0-10% (preferably at least 1%) thixotropic agent, and 0-20% densifying or cosmetic charges. From an application perspective, the compositions may contain antiperspirant or deodorant actives, antisepsics, hemostatic agents, antibiotics, protecting polymers, cicatrising agents, hormones, and other materials capable of being absorbed through the skin.

Other related materials include higher viscosity dimethicone, dimethiconol and silicone gum. The latter are based on high molecular weight PDMS endblocked with silanol or trimethylsiloxy groups. Because of their higher molecular weights, these materials can be used to form more lasting, substantive films on the skin. With increasing molecular weight the silicone may appear tacky to the touch, until it eventually assumes the characteristics of a more firm silicone gum. At these higher molecular weights, the silicone maintains its excellent spreading characteristics, which still impart a feeling of softness on the skin without greasiness.

Compounded with fillers such as silica or silicate resins, PDMS shows longer lasting film-forming properties (e.g., Dow Corning® 593 Fluid). In pharmaceutical applications, PDMS blended with silica is commonly known as simethicone. These materials are typically used for their film-forming properties as well as their complementary benefits such as anti-foams or lubricants (e.g., for siliconization of bottle stoppers or as lubricants for condoms). Silicone compounds can be used where substantive, film-forming and protective properties are intended. Emerging applications suggest their use in scar treatment.

Dimethicone Crosspolymers. An alternative to increasing molecular weight (as with silicone gums) or adding filler (as with silicone compounds) is to partially cross-link silicone polymers and disperse this material in an appropriate silicone carrier fluid (11). The resulting dimethicone cross-polymers (also known as silicone elastomers in the personal care industry) differ from basic PDMS because of the cross-linking between the linear polymers. These materials have potential applications for scar treatment, periwound protection and enzyme delivery.

In skin care applications, the aesthetics of silicone elastomers (including those with functional groups) and their ability to absorb various oils (with Dow Corning® 9506 Elastomer Powder) are two of the most important properties. Silicone elastomers have a skin feel unlike any of the silicone fluids. It has been described using terms such as smooth, velvety and powdery, and it can be modified by controlling the amount of liquid phase in the formula, and therefore the degree of swelling.

Due to their film-forming properties, dimethicone crosspolymers can be used as delivery systems for active ingredients such as oil-soluble vitamins and sunscreens. Sunscreens such as octyl methoxycinnamate can be more efficiently delivered from a formulation containing a silicone elastomer, producing a higher sun protection factor (SPF). The ability of the silicone elastomer blend to enhance SPF in oil-in-water sunscreen formulations containing organic sunscreens was evaluated through in vivo tests (12). Two prototype formulations were used; one with a combination of organic sunscreens and the silicone elastomer, the other with the same sunscreen active ingredients but without the silicone elastomer blend.

As Figure 3 shows, the addition of 4% silicone elastomer blend to a sunscreen formulation containing organic sunscreens can increase the SPF from 5.7 to 18. This property of the silicone elastomer allows formulators to maximize the effectiveness of sunscreen agents in a formulation while reducing their amount to achieve a desirable SPF. As a result, formulation costs can be reduced along with potential irritation caused by sunscreen actives. Or, from another perspective, formulators can reach a higher SPF with the same amount of UV absorber, resulting in enhanced product claims with no added formulation cost.

Silicone elastomers can be produced from linear silicone polymers by a variety of cross-linking reactions. Figure 4 shows the preferred approach, a hydrosilylation reaction in which a vinyl group reacts with a silicon hydride.

Figure 5 illustrates the general process whereby linear silicone polymers with reactive sites along the polymer chain react
The dimethicone crosspolymer can be produced either as a gel made of a suspension of elastomer particles swollen in a carrier fluid (e.g., Dow Corning® 9040 Silicone Elastomer Blend), or as a spray-dried powder (Dow Corning® 9506 Elastomer Powder).

The first and most popular carrier for the gel form is cyclomethicone, but low viscosity dimethicones and organic fluids can also be used. Examples of dimethicone crosspolymers in the suspension or gel form are Dow Corning® ST-Elastomer 10 or Dow Corning® 9040 Silicone Elastomer Blend, which typically have an elastomer content ranging from 10 to 20% by weight. These materials can be handled easily by simple pumping. Subsequent silicone elastomers are made using other carriers or with the addition of functional substituents. Additional refinements in processing have produced silicone elastomer blends with different particle sizes.

Among the materials with functional groups are silicone elastomers based on dimethyl silicone polymers that contain polyethylene oxide substituents (e.g., Dow Corning® 9011 Silicone Elastomer Blend). The presence of these polar moieties and the low cross-link density of the elastomer make it an effective emulsifier for preparing water-in-silicone emulsions. The resulting material provides a more hydrophilic system that can be easily adapted to drug delivery applications.

An example of a dimethicone crosspolymer based on an alternative carrier contains a low viscosity dimethicone in place of cyclopentasiloxane (Dow Corning® 9041 Silicone Elastomer Blend). The dimethicone carrier is essentially nonvolatile, making the material useful in applications where it is desirable for the elastomer properties to be constant after application. The skin feel does not change over time because the elastomer remains swollen in the carrier. This gives the dimethicone-based silicone elastomer a long-lasting effect on the skin compared to the cyclopentasiloxane-based variety.

Another dimethicone crosspolymer (Dow Corning® 9546 Silicone Elastomer Blend) was developed to capitalize on the synergistic effects that can be achieved using a combination of a silicone elastomer in the gel form (dispersed/swollen in a silicone fluid) with silicone elastomer powder. The mixture of the swollen gel particles and the swollen spherical elastomer particles offers an additional option for skin feel.

Silicone Emulsions. Another approach to providing increased film cohesiveness is by incorporating active ingredients in an aqueous emulsion of ultra high molecular weight silicone (Dow Corning® HMW 2220 Non Ionic Emulsion). Tests of wash-off resistance measure the durability of this silicone as deposited from a wet wipe in the presence of a solution of sodium laureth sulfate. This method uses an infrared spectrophotometer and Fourier transform (FTIR) technique along with a skin analyzer device to conduct direct measurements of the quantity of silicone remaining on the forearms of panelists (14). Results from the prototype wipe formulation are compared with a commercial benchmark in Figure 6, where data from three washes indicate that the wipe containing an emulsion of ultra high molecular weight dimethicone offers the best wash-off resistance (15).

In addition, pre-emulsified concentrates of silicones, some of which have high molecular weights and viscosities, can be delivered as high internal phase (HIP) emulsions (16). In their neat form, emollients and moisturizers such as silicone gums and high molecular weight fluids can be difficult to emulsify, and they have a tendency to separate from the system during the formulating process. The pre-emulsified concentrates (e.g., Dow Corning® 7-3100 Gum Blend HIP Emulsion and Dow Corning® 7-3099 Dimethicone HIP Emulsion) provide versatility and formulation flexibility, and they allow for combinations of silicone and organic materials. Emulsions made with the new technology are characterized by small particle size and size-distribution control, which allow formulators to create skin care products with distinctive aesthetics.

Good aesthetics and emolliency in finished products depend in part on formulations that deposit a uniform concentration of emollients and moisturizing ingredients. Because of the excellent stability associated with HIP emulsions, formulators can easily adjust emollient levels to obtain the skin feel they require. In addition, the small particle size of these ingredients makes them well suited for preparing clear moisturizing or skin treatment gels. Overall, the formulation benefits associated with HIP emulsions can be key to the relationship between aesthetics, patient compliance and treatment outcome.

Complementary Properties: Organofunctional Silicones

The film-forming properties of linear PDMS can be adapted to meet specific needs such as greater hydrophilicity and occlusivity by adding various organic groups to the silicon-oxygen backbone. These might include alkyl, phenyl, amine, polyether or other groups. For example, the addition of tri- and tetra-functional Si-O structures can be used to form silicone resins for improved substantivity and to modify feel. These materials also are used in pressure sensitive adhesives. The addition of ethylene oxide or propylene oxide polymer chains can aid emulsification during formulation and improve compatibility with polar materials.

Alkylmethysilosxane (AMS). The water vapor permeability of a material is a very important property for wound care applications. In many applications, it is desirable to have materials with high permeability. With silicones, it is possible to formulate highly protective creams and lotions that are also suitable for wound care.
permeable. In other applications, it can be advantageous to modify the permeability of an applied film to reduce water loss. Pure PDMS materials are always permeable because of their structure. By adding hydrocarbon chains to the silicone backbone, the permeability of these silicones can be modified, and the resulting AMS materials have permeability that can be controlled.

The addition of alkyl groups to PDMS allows hybrid-like properties between traditional silicone and organic capabilities. These developments have led to new waxes and fluids (e.g., Dow Corning® ST-Wax 30, Dow Corning® Emulsifier 10, Dow Corning® AMS-C30 Wax and Dow Corning® 2502 Cosmetic Fluid) with film-forming properties that can also be used to alter the rheology of formulations. Use of this technology can provide tools for the formulator to adjust the occlusivity of a film without significantly impacting its substantiveity.

Because AMS materials are commonly used in personal care products, they can provide similar performance and sensory attributes in topical health care applications and wound care applications, such as skin-protective films for areas surrounding wounds and areas constantly wet by body fluids (e.g., incontinence). Depending on the product application and required benefits, formulating chemists can select the most appropriate materials.

To form these fluids and waxes, alkyl groups of different chain lengths are chemically substituted for methyl groups on the siloxane backbone. The reactions form silicone-organic copolymers that may contain sufficient organic content to change several of the physical and chemical properties normally associated with PDMS, including water vapor transmission and permeability, organic compatibility and organic substrate substantiveity (17).

PDMS modified with C30-45 alkyl groups has also shown a moisturizing effect similar to that of petrolatum (17). AMS materials also demonstrate enhanced film barrier formation compared to PDMS, and they can be incorporated in topical skin formulations to form films with greater substantivey and wash-off resistance versus those of PDMS (8).

Varying degrees of alkyl substitution on the silicone backbone result in wax-like materials with a range of melting points. When added to emulsions for topical products, these waxes can alter rheology, providing improved product performance and stability of water-in-silicone creams. Studies demonstrate that although the wax increases the viscosity of water-in-oil systems, it does not negatively affect sensory performance.

The Silicone Solution for Long-Lasting Films

Silicone technologies can be used to provide a balance of adhesive properties and cohesion for long-lasting films.

Pressure Sensitive Adhesives. Silicone pressure sensitive adhesives (PSAs) for medical applications are viscoelastic compounds based on the condensation of PDMS polymer on silicate resins. PSAs do not require additives such as antioxidants, stabilizers, plasticizers or additional catalysts or other potentially extractable ingredients. They are produced by condensing dimethiconol with silicate resin in the presence of ammonia, as shown in Figure 7. The dimethiconol (in the form of a silanol end-blocked PDMS) as the viscous component of the viscoelastic structure, impacts the wetting and spreadability properties of the adhesive. The resin acts as a reinforcing agent, tackifying the fluid as well as contributing to the elastic component of the rheology. Resin content is the major factor for enhancing cohesion to the required level to obtain the optimum balance of tack, adhesion and peel release (18).

The hydroxy groups on both the silicone fluid and resin are condensed in the presence of ammonia and heat to produce the standard version of silicone PSA, represented by the BIO-PSA® 7-4400, 7-4500 and 7-4600 series adhesives from Dow Corning. Subsequent heat treatment at reduced pressure removes ammonia and the processing solvent. Small amounts of reactive hydroxy groups remain in the standard adhesive and can be significantly reduced by reacting them with a trimethylsilyl endcapping agent (e.g., hexamethyldisilazane, as shown in the figure). This end-capped adhesive is.

Figure 6. FTIR evaluation of wash-off resistance from silicone-treated wet wipes (15).

Figure 7. Synthesis of standard and amine-compatible silicone PSAs (19).
regarded as “amine compatible” because it exhibits enhanced chemical stability in the presence of amines, a component of many therapeutic agents (19-21). Examples of amine-compatible silicone PSAs include the BIO-PSA® 7-4100, 7-4200 and 7-4300 series adhesives from Dow Corning.

Dow Corning’s medical grade silicone PSAs are nonreactive systems that flow slightly under light pressure at skin temperature to conform to the stratum corneum (22). They are recognized as suitable adhesives for adhering medical pharmaceutical devices on skin, providing the opportunity for use in medical adhesive devices, tapes, and bandages, wound dressings and drug delivery system applications. They can provide the following benefits:

- Suitable tack for quick bonding to various skin types, including wet skin
- Suitable adhesive and cohesive qualities
- Long-lasting adhesion to skin (potentially up to seven days)
- High degree of flexibility
- Permeability to moisture
- Compatibility with many therapeutic molecules
- Coformulation with pharmaceutical excipients to adjust the kinetics of drug release

**In Situ Cure Elastomer Films.** These films are based on silicone elastomer formulations that cure at room temperature within a few minutes. Refined for skin-contact applications, they can be applied as a liquid formulation that cures to an elastomeric film directly on the body. Two silicone cure technologies, condensation and hydrosilylation, have been used to develop these materials.

**Condensation Technology**

Film-in-place technology employs a network of cross-linked methoxy-functional PDMS, which is formed by rapid titanate-catalyzed condensation curing at room temperature. A treated silica filler is incorporated for reinforcement, cohesion and durability. The volatile hexamethyldisiloxane carrier acts as a delivery vehicle and aids spreadability of the cream-like mixture. After the quick process of coating, drying (about two minutes) and curing, the result is a tack-free rubber film. Adhesion, drying time and surface texture can be adapted for individual applications. The film is soft, flexible and elastic for gentle adhesion to skin. It may also be used as a matrix for loading and delivery of active ingredients.

The material cures in contact with many materials including skin and wet surfaces. Consistent with other chemistries, the addition of certain additives may impact the cure and final physical properties of the elastomer. As such, a case-by-case assessment is warranted to ensure compatibility of various additives with the elastomer.

The film-in-place technology is available from Dow Corning as two experimental materials:

- **Dow Corning® 7-5300 series Film-in-Place Coating, a one-part product**
- **Dow Corning® 7-5310 Base and Dow Corning® 7-5311 Curing Agent, a two-part product**

Both the one- and two-part systems are easy to use. In both cases, the material is applied to its substrate by spray-coating or dispensing and spreading. The coating is allowed to dry and cure at room temperature. Both one- and two-part systems can be loaded with active ingredients, but considering the need to protect the one-part material from contact with moisture before application to the coating site (skin), coformulation with actives and excipients would be easier to accomplish with a two-part system. The two-part system can then be converted to a one-part system by blending.

This technology supports applications such as in situ films and coatings. Other applications include delivery systems for active ingredients in topical therapeutic systems or wound dressings.

**Hydrosilylation Cure**

Fast cure, low consistency silicone elastomers use a hydrosilylation cure, based on the addition of a hydrogen-functional siloxane to vinyl-functional PDMS, as described in the paragraph related to dimethicone crosspolymer.

Systems based on parts A and B are designed for mixing at a 1:1 ratio, although other mixing ratios can be considered. The base, or part A, comprises a reinforced silicone phase that includes vinyl-terminated PDMS, treated silica and a platinum catalyst. The addition curing agent, or part B, contains vinyl-terminated PDMS, treated silica and a methylhydrogen siloxane cross-linking agent.

The following products are available from Dow Corning as experimental materials:

- **Dow Corning® 7-FC4210, series parts A and B.**

These products form two-part silicone elastomer formulations for thermostable silicone rubber systems. The materials are fast curing at room temperature (i.e., from 2 to 30 minutes), and their properties suggest use in in situ film-forming or controlled release systems.

The silicone elastomer systems are easy to use in formulation, and coformulating ingredients may be added to the system. Depending on the individual application, relevant active ingredients or excipients should be thoroughly dispersed in either part A, part B or both. The two parts are combined and mixed at room temperature, then applied and allowed to cure, also at room temperature. Like the film-in-place materials, the uncured silicone elastomer has the consistency of a cream, and the properties can be adjusted based on mixing ratios. The resulting films are networks of cross-linked and reinforced PDMS that are soft, flexible, elastic and cohesive, allowing for gentle adhesion to skin and a low peel release force. These films may be used as matrices for loading and delivery of active ingredients in topical therapeutic systems, wound dressings or skin care products.

**Silicone-Organic Film Formers**

Finally, complementary and synergistic benefits can be obtained with silicone-organic combinations, which might be simple blends or copolymers. Among these materials are silicone polyamides, silicone-acrylic hybrids and silicone-plasticized nitrocellulose. Silicone polyamides, a new family of materials, offer increased durability on the skin.

**Nitrocellulose and Silicone.** Previous studies have reported that a plasticized combination of PDMS, nitrocellulose and castor oil imparted skin protectant properties that were resistant to wash-off (23).

**Silicone Acrylate Copolymers.** The literature suggests that there is potential for an experimental family of silicone and organic hybrid materials in film-forming applications. These materials can be based on a silicone material that is a vinyl-type polymer with a carbosiloxane dendrimer structure in its side molecular chain. The polymer may or may not contain fluorinated organic groups (24,25).

The new materials offer enhanced durability and improved aesthetics. The combination of the organic component together with the silicone portion produces distinctive properties of each material type.

Early evaluations indicate the ability of the silicone acrylate copolymers to form a durable film that is resistant to abrasion and wash-off. In tests with prototype sunscreen formulations, the silicone materials help the sunscreen remain on the skin after simulated washes.
The Future for Silicone Film-Forming Technologies

The current wound care market is a $9.5 billion segment in the health care industry, and it continues to grow based on trends in scar management, liquid bandage development, the need for gentle adhesion and delivery of active ingredients. In general, the market is faced with unmet needs in terms of adhesion, substrates and delivery of active ingredients, all of which provide opportunities for silicone-based films. Ongoing research in silicone film-forming technologies holds potential for a range of innovative applications that can provide optimum care for patients. The unique film-forming characteristics of silicones make these materials vital components for influencing aesthetics, patient compliance and treatment outcomes associated with new health care products.

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