



Dow Corning®
Solutions
for Scar Care

Skin care expertise for wound care applications

Dow Corning® Solutions — endless possibilities for scar management

Dow Corning's leadership in the health care field is matched only by its 50-plus years of skin care formulation expertise. By bringing the two together, we're unfolding countless possibilities for scar management therapies—and we know this is just the tip of the iceberg.

We want to put our know-how to use by collaborating with you. Starting with its unique silicone technology platform, Dow Corning will help you develop effective and aesthetically superior scar therapies in the finished product. Dow Corning offers cost-effective solutions to meet market demands, without sacrificing your need for more technologically advanced products.

Proven Time and Time Again

An international panel of scientists and experts on scarring determined that the standard for preventing and treating abnormal scars are therapies using silicone gel sheeting and intralesional corticosteroids. (See Mustoe, T.A.: "International clinical recommendations on scar management," *Plastic & Reconstructive Surgery*, 2002 Aug; 110:560-71.)

Results from a meta-study of 27 separate trials demonstrate that silicone gel sheeting is more effective than other occlusive dressings (e.g. polyethylene, polyurethane) and showed no significant adverse effects.⁷

Dow Corning Proven Solutions — keeping pace with your innovations

The proven ability of Dow Corning silicone materials to serve as delivery vehicles for the topical application of synthetic drugs and biologics provides possible synergies with known or emerging anti-scarring therapies.

Scar therapy devices on the market adhere to the skin with secondary dressings, films and non-wovens. Dow Corning offers a range of **adhesives** that remain constant for extended periods, even under high-humidity conditions. The safety of these materials is supported by laboratory testing, and by their extensive use in health care applications. Dow Corning's Soft Skin Adhesive technology (for example, Dow Corning® 7-9800) is the basis for current gel sheeting therapy.

Dow Corning's **Silky Touch** line of silicon-based excipients (qualified for use in topical pharmaceutical formulations) may be used in drug delivery applications. These products have enhanced drug permeation properties to facilitate the loading, stabilization and release of actives on the skin.

Dow Corning's line of **Dimethicone NF (Dow Corning® Q7-9120 series) Fluids** are well suited for our customers who use dimethicone as an active ingredient in their formulation and choose to make skin protectancy claims with their skin care product. Refer to the Code of Federal Regulations "21 CFR Part 347: Skin Protectant Drug Products for Over-the-Counter Human Use" final monograph for specific details describing the use of dimethicone for skin protectancy claims, or call Dow Corning to learn more!

A recent innovation from Dow Corning is referred to as **New Scar Technology (NST)**. NST is patented technology composed of silicone gum, silicone fluid, silicone wax and silicone volatiles. This film is non-tacky, substantive and semi-occlusive. Additionally, this technology can also be used to deliver pharmacological and cosmetic ingredients.

Dow Corning® Alkylmethyl Siloxanes provide multifunctional benefits including improved substantivity, occlusivity, lubricity and detackification. You can also use Dow Corning® Alkylmethyl Siloxanes to formulate lotions and ointments. Did you know, Dow Corning® Alkylmethyl Siloxanes have been used for years in the personal care market and are a key ingredient in many premium brands?

Additionally, Dow Corning supplies a range of **Silicone Elastomer and Dimethicone** product options that are appropriate for a range of skin care applications, including lotions and ointments for scar therapy products. Dow Corning silicone elastomers can improve the aesthetics as well as modify the rheology of your formulation. Our dimethicone products can improve spreadability, while providing substantivity and a soft skin feel.

Dow Corning offers you a full range of affordable scar therapy solutions available today, or customized to your specific needs tomorrow. We also help you invent the future when we innovate together. Give us a call—our global offices are listed on the back of the brochure—we welcome the opportunity to put our technology, material and formulation expertise to work for you.

Dow Corning® Solutions for Scar Care

Skin care expertise for wound care applications

Performance-enhancing Materials Appropriate for Health Care Innovation

Dow Corning, a long-term leader in the health care industry, continuously enhances the performance of its materials to optimize them to meet our customers' needs. Scar therapies can benefit from our experience with skin care formulations and the efficacy of silicones in delivering multifunctional benefits—including delivery of actives. Dow Corning has an FDA-registered and inspected facility dedicated to health care material manufacturing.

At Dow Corning, we believe that there are many uses for silicones in scar therapies—film forming, moisturizing, occluding, adhesion, sheeting, delivering actives, etc. Our expert resources can help you invent the future for scar management.

This paper reflects some of the uses we anticipate for silicones in the growing scar therapy market. However, where we've been most successful, is in collaboration with our customers, providing solutions that meet your needs.

Abnormal Scarring

Hypertrophic scars and keloids are fibrotic conditions that result in an over-deposition of collagen in the skin. They can be caused by minor cutaneous perturbations such as ear piercing or acne, or by traumatic injuries such as burns. Visually, these scars are raised reddish nodules that can cause pruritus, pain, restricted movement, and cosmetic disfigurement. The principal difference distinguishing keloid from hypertrophic scarring is that a keloid progressively invades the surrounding healthy tissue. In contrast, a hypertrophic scar only increases in dimension by pushing out its margins; there is no expansion into the surrounding tissue. Whether the scar is hypertrophic or keloid, the scar tissue rarely extends deep into the dermis.

It is well documented in published literature that various factors including ethnic background, hormonal status and injury loca-

tion can contribute to a heightened incidence of scarring. Keloids are more prevalent in individuals with darker skin pigmentation, with an incidence of 4.5 - 16% in African and Hispanic populations^{1,2}. Of note, data from the National University of Singapore indicates that keloids are three (3) times more common in Chinese patients than among Caucasian patients (<http://www.med.nus.edu.sg/sur/keloid.html>). Another study in the published literature suggests that Chinese are slightly more prone to keloids than the darker-skinned Indians and Malays³. Hypertrophic scars are more common and occur with equal frequency in all racial groups.

The average age of onset for keloids has been estimated to be approximately 22 years for both men and women⁴. Others report a higher incidence in young women relative to age-matched males, which may reflect a higher frequency of ear lobe piercing among women. Specific body sites that are more prone to scarring are areas with oil-secreting sebaceous glands or areas of increased skin tension. They include the shoulders, upper back, upper arms, chest, ears, cheeks and neck. Hypertrophic scars can regress over time, whereas spontaneous regression of keloids is rare.



Overall Benefits of Silicone

Among qualified materials used in health care applications, silicones are clearly recognized for their biocompatibility. Dow Corning's health care products have a long history of clinical use to support their biocompatibility.

Additionally, silicone chemistry offers a broad range of performance characteristics that make Dow Corning materials suitable for use in many types of processes and applications, ranging from multifunctional excipients and active pharmaceutical ingredients to medical device components.

Silicone Solutions for Scars

A variety of techniques have been utilized to prevent, as well as treat, abnormal scars. The standards for preventing and treating abnormal scars are therapies using silicone gel sheeting and intralesional corticosteroids⁶. Clinical studies have proven that silicone gel sheeting is safe, and is superior to polyethylene, polyurethane and other occlusive dressings⁷. Although less studied, formulations of silicone fluids have also demonstrated efficacy on minor hypertrophic scars^{8,9}. Whether this beneficial response is due in part to silicone-induced skin hydration is at present unknown.

A number of other treatment modalities have also been explored (e.g. topical or intralesional steroid applications, ultrasound, cryotherapy, compression therapy, radiotherapy,

and laser therapy), but few have been supported by controlled clinical studies. Surgical excision can result in recurrence, as the new surgical wound is prone to the same mechanical, immunological and biochemical forces as the original scar. In general, hypertrophic scars appear to be more responsive to treatment than keloids⁵.

Dow Corning Skin Care Heritage

For more than 50 years, Dow Corning silicones have been formulated into skin care applications. In the early 1950's, silicones were used in diaper rash creams and hand protectants. Today, silicones are used in 1 out of 2 personal care products on the market, because they provide such unique aesthetic and delivery benefits, such as:

- Moisturization
- Humectancy
- Occlusivity
- Emolliency
- Water barrier and improved wash-off resistance
- Improved aesthetics

Customers around the world choose Dow Corning for our formulation expertise, our regulatory expertise, our dedicated FDA registered healthcare facility, our Good Manufacturing Practices, our Responsible Care[®] policies, and our global supply chain.

Here's an example to demonstrate a scar therapy application with an existing Dow Corning product that's used widely in personal care products. Dow Corning[®] Alkylmethyl Siloxanes provide multifunctional benefits including improved substantivity, occlusivity, lubricity and detackification—qualities often sought in scar therapies.

You can also use Dow Corning[®] Alkylmethyl Siloxanes to formulate lotions and ointments. Call any of the locations listed on the back on the brochure; our customer service representatives are happy to provide you with formulations or any other needs.

New Product Development: Synergies with Other Anti-scarring Therapies

The proven ability of silicone materials to serve as delivery vehicles for the topical application of synthetic drugs and biologics provides for possible synergies with known or emerging anti-scarring therapies. Recently developed anti-scarring therapies include actives such as hyaluronic acid, interferon alpha-2b, decarin, tamoxifen, manose-6-phosphate, and imiquimod¹⁰⁻¹¹.

Delivery of Actives

Silicones have historically demonstrated their utility as delivery vehicles. Dow Corning has commercialized a line of products—Silky Touch—to provide enhanced drug delivery. These products are silicon-based excipients qualified for



topical pharmaceutical formulations. Dow Corning Silky Touch products provide drug substantivity, drug release, and distribution of active ingredients on skin (stratum corneum, epidermis and dermis). You can read more about these results by downloading *Silicones as Excipients for Topical Pharmaceutical Applications*, available on our website (www.dowcorning.com/healthcare – click on the link to our Technical Articles).

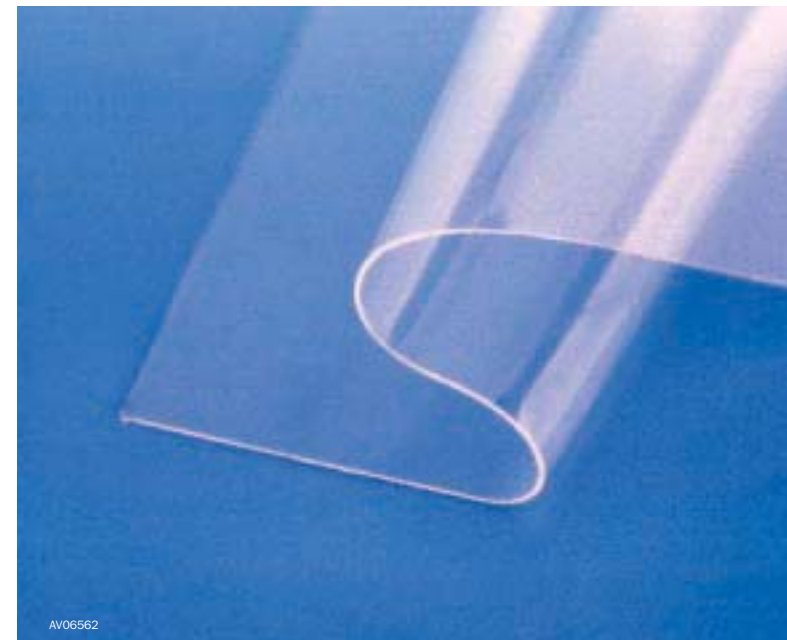
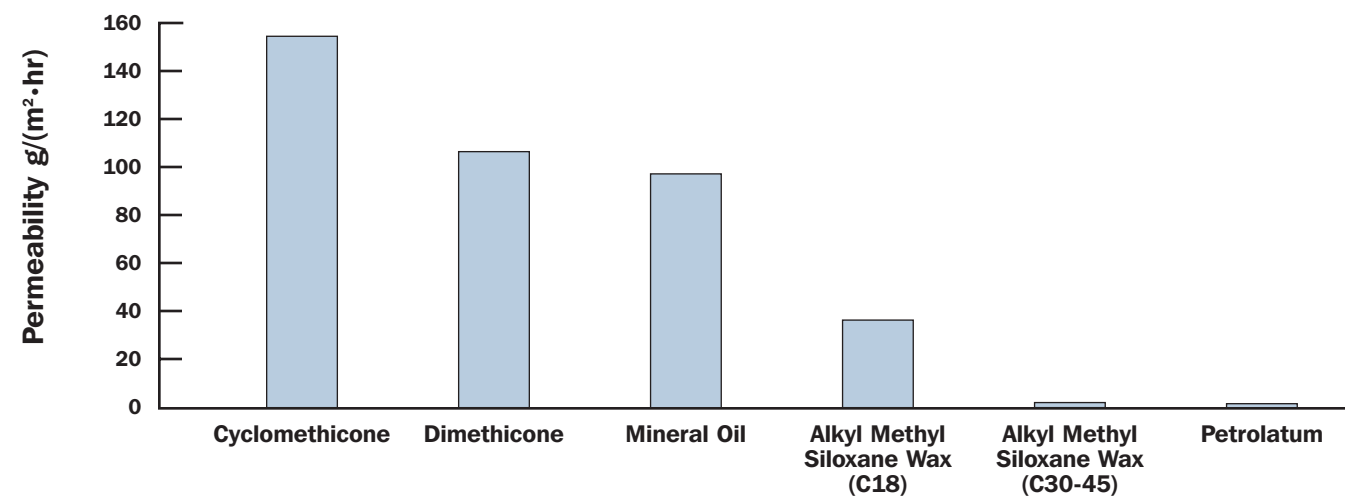
Gentle Skin Adhesion

Today, there are scar therapy devices on the market that are attached to the body with secondary dressings. Other commercial scar therapy devices, films and non-wovens, are adhered directly to the skin. Dow Corning offers a range of adhesives to meet this need.

New Scar Technology (NST)

Another innovation from Dow Corning is New Scar Technology. This combination of silicone materials leaves a film on the skin that is non-tacky, substantive and semi-occlusive. Consider the opportunities for using this technology to deliver actives, such as pharmacological and cosmetic ingredients as well. If the commercialization of this technology interests you and your company, please contact us to further discuss future collaborative activities.

Water Vapor Permeability



Patents

The following list of patents represents only a few selected references from the public domain. This list is not all-inclusive.

Patent #	Publication Date	Company	Title
EP 0 300 620 B1	June 24, 1992	Dow Corning France	Surgical Dressing
WO 01/22923 A2	April 5, 2001	Dow Corning France	Scar Treatment Composition
WO 01/96450	July 3, 2003	Dow Corning Corporation	Fast Cure Film Forming Formulation

Combination of certain materials listed in this brochure are described in the above patents and are subject to limitations of practice due to current licensing agreements.

Scientific References for Scar Therapies

1. B.J. Abrams, A.V. Benedetto, and H.M. Humeniuk. Exuberant keloidal formation. *J Am Osteopath Assoc* 93: 863, 1993.
2. W.B. Rockwell, I.K. Cohen, and H.P. Ehrlich. Keloids and Hypertrophic Scars: A Comprehensive Review. *Plast Reconstr Surg* 84: 827, 1989.
3. S. Alhady and K. Sivavatharajah. Keloids in Various Races. *Plast Reconstr Surg* 44:564,1969.
4. B. Cosman, G.F. Crikelair, M.C. Ju et al. The Surgical Treatment of Keloidal Scars. *Plast Reconstr Surg* 27:335, 1961.
5. S.V. Pollack and J.B. Goslen. The Surgical Treatment of Keloidal Scars. *J Dermatol Surg Oncol* 8:1045, 1982.
6. Thomas A. Mustoe, Rodney D. Cooter, Michael H. Gold et al. International Clinical Recommendations on Scar Management. *Plast and Reconstr Surg*, 110: 560-571, 2002.
7. J. Posten. The Use of Silicone Gel Sheeting in the Management of Hypertrophic and Keloid Scars. *J. Wound Care* 9:10, 2000.
8. Y. Sawada and K. Sone. Treatment of Scars and Keloids with a Cream Containing Silicone Oil. *Br. J. Plast Surg* 43: 683, 1990.
9. T.W. Wong, H.C. Chiu, C.H. Chang et al. Silicone Cream Occlusive Dressing: A Novel Non-invasive Regimen in the Treatment of Keloid. *Dermatology* 192: 329, 1996.
10. M.A. Kuhn, M.R. Moffitt, P.D. Smith et al. Silicone Sheeting Decreases Fibroblast Activity and Downregulates TGFβ2 in Hypertrophic Scar Model. *Int J Surgical Investigation* 2:467, 2001.
11. B. Berman and J. Kaufman. Pilot Study of the Effect of Postoperative Imiquimod 5% Cream on the Recurrence Rate of Excised Keloids. *J Am Acad Dermatol* 47:S209, 2002.

Drug Delivery Capability of Silicone Materials

- Silicones in Pharmaceutical Applications. Aguadisch, Louis; Colas, André. *Chim. Nouv.* (1997), 15(58), 1779-1788.
- Loosely Cross-linked Silicone Elastomer Blends and Topical Delivery. Gantner, David C.; Smith, Janet M.; Thomas, Xavier; Lin, Zuchen. *Advanced in Controlled Drug Delivery; Science, Technology, and Products; ACS Symposium Series 846*; Ed. Dinh, Steven M.; Lui, Puchun. (2003), Chap. 9, 113-127.
- Effects of Nonionic Surfactants and Excipients on the Drug Dissolution and Physicochemical Properties of Silicone Adhesives. Raul, Victor A.; Thomas, Xavier. *Controlled Release Society 30th Annual Meeting Proceedings #565* (2003).

Other References

- Facial Care & Color Cosmetics Product Selector Guide: Form Number 27-1057-01
- Silky Touch: Form Number 52-1026-01
- Silicones as Excipients for Topical Pharmaceutical Applications: Form Number 52-1034-01
- Alkylmethyl siloxanes: A Novel Family of Silicone-Organic Hybrid Polymers for the Cosmetic Industry: Form Number 25-272-01
- Experience the Difference: Skin Feel and Texture CD-Rom; Form Number 27-1087-01
- Experience the Difference 9045 and 9546 Silicone Elastomer Blends: Form Number 27-1099-01
- Class VI Elastomer Brochure: Form Number 51-997A-01
- The Understanding of Factors Influencing the Permeability of Silicones and Their Derivatives: Form Number: 22-1534A-01
- Dow Corning Web Site: www.dowcorning.com

Product Classification	Dow Corning Product Nomenclature	Delivery of Actives potential	Film Forming on Skin	Moisturizing/Occlusive	Adhesive	Solid Devices/Sheeting
Dimethicone	• 200 Fluids (range of viscosities)		X	Non-occlusive		
	• Q7-9120 (20, 100, 350, 1,000, and 12,500cSt) (Silky Touch)	X	X	Semi-occlusive		
Dimethicone Silicone Gum Fluid Blend	• 1501 Fluid		X	Semi-occlusive		
	• 1503 Fluid		X	Semi-occlusive		
	• ST-Dimethiconol 40 (Silky Touch)	X	X	Non-occlusive		
	• Dimethiconol Blend 20 (Silky Touch)	X	X	Non-occlusive		
Volatile Silicone	• Silmogen Carrier (Silky Touch)	X	X	Non-occlusive		
	• Q7-9180 Silicone Fluid (0.65cSt and 1.0cSt) (Silky Touch)	X		Volatile		
	• ST-Cyclomethicone 5 – NF (Silky Touch)	X		Volatile		
Elastomer	• Class VI LSR	X		Semi-occlusive		X
	• Class VI HCRs	X		Semi-occlusive		X
Elastomer Blend	• 9040 Silicone Elastomer Blend		X	Semi-occlusive		
	• 9041 Silicone Elastomer Blend		X	Semi-occlusive		
Fillerless Elastomer	• ST-Elastomer 10 (Silky Touch)	X		Semi-occlusive		
	• 7-9600 Soft Filling Elastomer			Semi-occlusive	slightly	X
Fast Cure Elastomer	• 7-5300 Film-in-Place Coating (Developmental)	X	X	Semi-occlusive	slightly	X
	• Silastic MDX4-4210 Medical Grade Elastomer	X	X	Semi-occlusive	slightly	X
Cured Elastomer Film	• 7-4107 Elastomer Membrane			Semi-occlusive		X
Skin Adhesive Elastomer	• 7-9800 SSA	X		Semi-occlusive	X	X
Pressure Sensitive Adhesive	• MD7-4502 Silicone Adhesive (medium tack)		X	Semi-occlusive	X	X
	• MD7-4602 Silicone Adhesive (high tack)		X	Semi-occlusive	X	X
Silicone Polyamide	• Bio-PSA Silicone Adhesives	X	X	Semi-occlusive	X	X
	• 2-8178 Gellant		X	Semi-occlusive		
Silicone Emulsifier	• Emulsifier 10 (Silky Touch)	X	X	Non-occlusive		
Silicone Polyether	• 2501 Wax		X	Non-occlusive		
Silicone Wax	• Silky Wax 10 (Silky Touch)	X	X	Occlusive		
	• ST-Wax 30 (Silky Touch)		X	Occlusive		
	• 2502 Cosmetic Wax					
	• 2503 Cosmetic Wax					
	• AMS C-30					
	• 580 Wax					

Developmental samples are subject to sampling limitations; contact Dow Corning for more information if these products are of interest. Contact Dow Corning for additional product specification information.

You can count on Dow Corning for:

- **Trustworthy Regulatory Practices:** We strictly adhere to current appropriate manufacturing practices and specifications—Pharmacopoeia certifications, U.S. Drug Master Files, European Drug Master Files, ISO 10993-1 standards.
- **Reliable Source of Supply:** Dow Corning's integrated supply chain and comprehensive documentation ensure complete traceability of our materials.
- **Consistent Quality:** Our health care materials are manufactured in a dedicated, FDA-registered (CFN 1816403) and inspected facility that meet cGMPs and Responsible Care® policies.
- **Supportive Regulatory Practices:** In addition to delivering on the performance and the purity level your application requires, Dow Corning also manufactures and tests materials so that they comply with the industry's—and your geography's—stringent regulatory demands. We also offer Drug Master Files, European Technical Files and FDA Material Application Files for some materials, to help speed and simplify the regulatory process.
- **Supportive Services:** Dow Corning is available to help you make informed choices for a current product or custom formulated material. We offer a worldwide network of technical assistance centers, toxicological testing and analysis, material analysis, chemical engineering services, and more.
- **A Range of Beneficial Materials:** Dow Corning products have a long history of biotesting and clinical use to support their biocompatibility. Silicone chemistry also offers a broad range of performance characteristics that make Dow Corning materials suitable for use in many types of processes and applications, ranging from multi-functional excipients to active pharmaceutical ingredients to wound management therapies.
- **Innovative Solutions:** Dow Corning is meeting the market's need for excipients that improve the aesthetics and bioavailability of topical pharmaceuticals, while collaborating with customers all over the world to expand the use of elastomers and adhesives for wound care. What will tomorrow bring? Countless opportunities to build upon the proven technology of our materials and our expertise, in the context of your product needs.

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