

**Silicone Materials for Topical Applications:
Meeting the Specialized Needs of
Evolving Market and Regulatory Requirements**

V. Caprasso, M. Eeman,
T. Gorski, F. Lin, K. Ulman



DOW CORNING



Silicone materials have a use history of more than 60 years in healthcare applications because of their wide biocompatibility profile, suitable biodegradability, and outstanding versatility. These characteristics continue to stimulate the creativity and interest of formulators for emerging applications.

Silicone – the Foundation of Innovation

Silicones are polymeric materials with a molecular structure formed by a chain of alternating silicon and oxygen atoms. The most common silicone polymers include various forms of polydimethylsiloxane (PDMS), where the strong polar backbone of Si-O bonds is characterized by apolar methyl groups attached to the silicon atoms. The length of the Si-O chain determines the viscosity of the silicone fluid, with the highest molecular weights related to gum-like materials. A broad category of silicone forms can be derived from PDMS polymers, including silicone gum blends, emulsions, elastomers, and resins. Because of these specific Si-O bonds shielded with methyl groups, PDMS is permeable to water vapor and capable of forming a breathable film on the skin.

Dow Corning has historically offered topical silicone products targeted for use as pharmaceutical excipients in formally reviewed drug products. In addition, Dow Corning has now developed a second product line of topical ingredients to serve the consumer health care market. These less-regulated topical ingredients

are targeted to cover a broad range of potential applications, from consumer products that do not contain an active pharmaceutical ingredient (API), to Class I or IIa medical devices, and over-the-counter (OTC) drug products produced to meet FDA OTC monograph requirements.

The Topical Care Market

Topical treatments are designed to treat a range of skin conditions. They are mainly marketed either as Rx (prescription) or consumer health care products (per above definition), as shown in Table 1.

Prescription market requirements include safely and effectively delivering the API to efficiently achieve pharmacokinetic and clinical relevance. In contrast, the requirements of the consumer health care market are more sensitive to the sensory aspects of a formulation. Efficacy with a pleasant feel helps patients be more compliant with their treatment.

The regulatory barriers to entry in both markets also are different:

- Globally, drug ingredients previously used in an approved

drug product, by a defined route of delivery, in the regions the drug is intended to be marketed, often facilitate approval of a drug product. In the US, these previously used ingredients by a defined route of delivery are often listed in the US FDA Inactive Ingredient Database (IID)

- For ingredients not previously used in an approved drug product by the same route of delivery, access to an excipient Drug Master File (US, Canada, Japan and China) or a customer Technical File (countries other than those previously noted) can be used to support drug product registration.
- In the consumer health care market, regulatory requirements are less stringent.

Table 2 summarizes the continuum of several topical forms commercialized to treat psoriasis. From prescription to companion products commercialized as cosmetics, dermatologists have a broad choice of treatments to recommend based on the severity of the disease. Also, when the product is commercialized as an

Table 1. Comparison of Market Segments for Consumer vs. Prescription Topical Care

	Consumer Health Care	Prescription
Main Segments	Analgesics Antifungals Acne Antiseptics Antipuritics Skin Condition	Infection Dermatitis Acne Psoriasis
Market needs	Pleasantly and rapidly improve skin conditions	Efficient in delivering drug
Regulatory Barrier to Entry	Low to medium	High

Table 2. Continuum of Topical Treatments for Psoriasis

	Definition	Patient Access	Examples for Psoriasis Treatment	Decreasing Regulatory Requirements
Branded (Rx)	<ul style="list-style-type: none"> • Prescription • Reimbursed • Patented drugs 	Prescription	<ul style="list-style-type: none"> • Dovonex®, Leo Pharma • NDA • API: calcipotriol at 0.05 mg 	
Generic (Rx)	<ul style="list-style-type: none"> • Prescription • Reimbursed • Out-of-patent drugs • Bioequivalence 	Prescription	<ul style="list-style-type: none"> • Calcipotriol – 0.05 mg, Glenmark Generics • ANDA • API: calcipotriol at 0.05 mg 	
OTC Drug (Non-Rx)	<ul style="list-style-type: none"> • Self medication • Not reimbursed • Known active • API within defined tolerance level 	<ul style="list-style-type: none"> • Consumer choice (OTC) • Pharmacist recommended (BTC) 	<ul style="list-style-type: none"> • Scytera™ Foam, Promius Pharma • GRAS Active: coal tar 	
Medical Devices	<ul style="list-style-type: none"> • Self medication • Not reimbursed • No pharmacological activity 	Consumer choice	<ul style="list-style-type: none"> • Dermalex® barrier cream, Omega Pharma • No API 	
Companion Products (Cosmetics)	Cosmetics	Consumer choice	<ul style="list-style-type: none"> • Avène® – Keratoreductor, Pierre Fabre • No API 	

OTC product, medical device or cosmetic, consumer choice is important, and consumer needs must be further understood.

When formulating these product classes, pharmaceutical and cosmetic companies have different regulatory and documentation requirements.

A Broader Offering for Targeted Applications

To serve customers with the appropriate product offering, Dow Corning provides three product lines to meet increasing regulatory requirements and documentation (Table 3):

1. Cosmetic ingredients developed to meet the needs of the cosmetic industry.
2. Topical ingredients developed to meet the needs of products

- designed for the consumer health care market.
3. Topical pharmaceutical excipients developed to meet the specialized needs of the pharmaceutical industry.

Together, these three product classes encompass the continuum of regulatory needs necessary to support topical formulations. Defined quality system require-

ments and dedicated regulatory packages have been developed for topical ingredient and topical pharmaceutical excipient materials:

- Topical ingredients are designed with a fit-for-purpose audit and an Ingredient Information Package (IIP), including Ingredient Regulatory Information (IRI) and an Elemental Impurities (EI) dossier.

Table 3. Three Topical Product Lines for an Evolving Marketplace

Cosmetic Ingredients	Topical Ingredients	Topical Excipients	
Increasing Regulatory Requirements and Documentation			
Cosmetic Products	Topical Medical Devices, Class I or IIa	Topical Over-the-counter Products*	Topical Regulatory-approved Products
Cosmetic	Consumer Health Care	Pharmaceutical	

* Over-the-counter drug products produced to meet FDA OTC monograph requirements

- Topical pharmaceutical excipients are aligned with excipient GMPs, documented in Product Regulatory Information (PRI) packages, and supported by regulatory files (e.g., DMFs, TFs and Certificates of Suitability/CEPs).

Dow Corning[®] brand topical ingredients and pharmaceutical excipients are both released from a defined manufacturing site that facilitates both raw material batch traceability and supply chain audit, two emerging demands from the consumer market to support their risk and quality management systems.

***Dow Corning*[®] brand Topical Pharmaceutical Excipient Product Line**

The well-established product line of topical pharmaceutical excipients serves the entire market of pharmaceutical applications. Figure 1 summarizes the various silicone material types available as excipients.

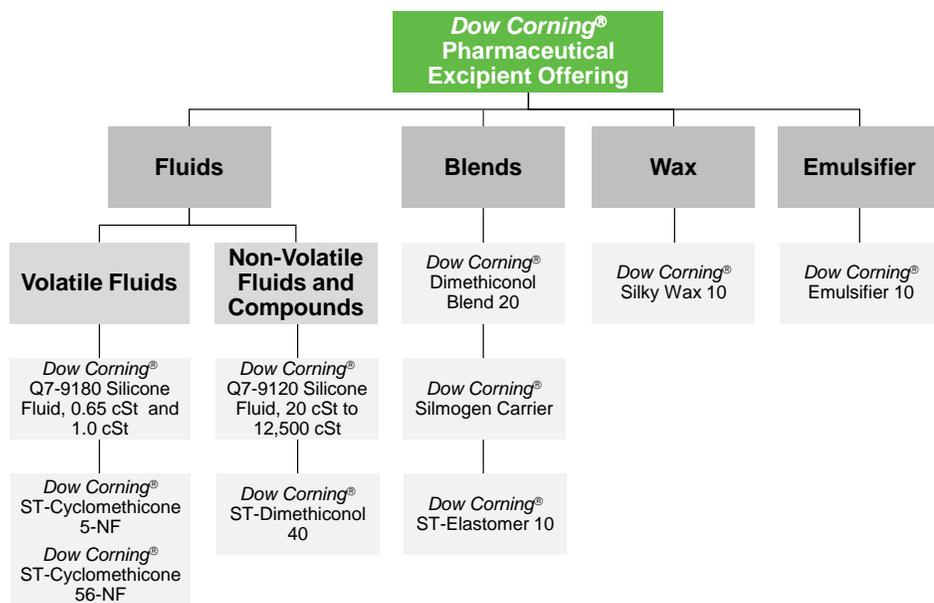
Increased quality and regulatory requirements for these products require higher levels of quality management system oversight, regulatory support and documentation. To meet these needs, Dow Corning establishes higher manufacturing controls and has developed more detailed regulatory packages with documentation specifically for its topical excipient line.

- **Product Regulatory Information:** a Dow Corning document that provides key regulatory information frequently requested by customers. May include description of quality systems in place, physicochemical information related to the specific product, compendium or monograph compliance, and other product information.
 - Technical Files summarizing items such as nomenclature, manufacturing, characterization, impurity profiles, specifications, test methods,

reference standards, packaging and stability.

- US Master Files and European Certificates of Suitability based on ICH CTD content for drug substance.
- Elemental Impurity dossier, which includes a summary of Inductively Coupled Plasma (ICP) Mass Spectroscopy (MS) results based on United States Pharmacopeia (USP) <233> methodology and ICH Q3D Table A2.2 allowable limits.
- **Summaries of Health Data or opinion letter:** documents that provide a formal summary of health data or opinion for specific Dow Corning products.

Figure 1. Silicone excipients for topical pharmaceutical applications are available in several major product forms: fluid, blend, wax and emulsifier



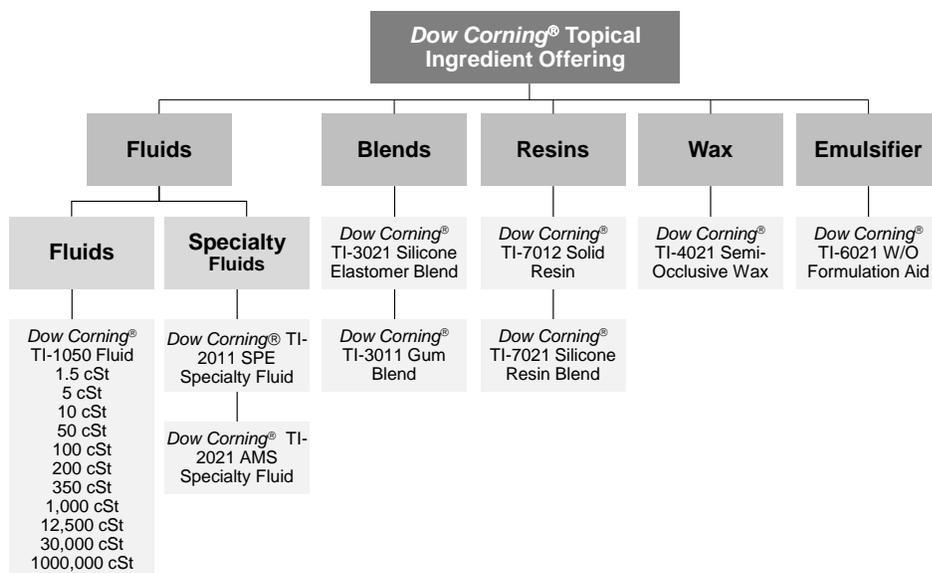
The Complementary Topical Ingredient Product Line

The continuum of health care regulatory requirements extends to consumer health care products that do not contain APIs (e.g., medical devices) and are OTC drug products produced to meet FDA OTC monograph requirements.

The *Dow Corning*[®] brand Topical Ingredient product line was developed to fulfill current regulatory demands for consumer health care products, which are subjected to less regulation than approved drug products. During development and commercialization of the Topical Ingredient portfolio, enhanced quality and supply chain requirements were applied to a range of silicone technologies covering silicone fluids, elastomer blends, gum blends, resins, silicone organic waxes and emulsifiers. The new topical offering enables innovation for a variety of product forms and textures and provides enhanced spreading and sensory characteristics with long-lasting effects. Combined with enhancements for quality, supply chain security and traceability, and regulatory documentation, this offering supports customer innovation and regulatory compliance needs.

Each topical ingredient is manufactured at a defined location that has been audited for safety (e.g., contamination control) and quality of the ingredient to be used in health care applications. Each batch of product also includes an identity test (infrared spectrum) and is warranted for elemental impurity levels based on ICH

Figure 2. A range of silicone materials are available for applications that depend on topical silicone ingredients



Q3D¹ Table A2.2 limits. In addition, ingredient regulatory information (IRI) packages, summaries of health data and an opinion letter are available to support product and regulatory needs.

To meet the expanding market for topical ingredients, Figure 2 shows a broad range of silicone materials.

Dow Corning Formulation Expertise in Topical Pharmaceutical Applications

When formulating for pharmaceutical applications, characteristics of the drug's delivery profile are key. Dow Corning uses the Franz diffusion cell method, whereby the device is equipped with a synthetic membrane or skin sample. This approach confirms the suitability

of the silicone-based matrices to release the loaded drug, allowing its efficient penetration into the epidermis, permeation through the different skin layers and resorption into the subcutaneous tissues or blood circulation according to the targeted therapeutic effect and receptors.

Formulations developed by Dow Corning have different delivery forms (e.g., emulsions, aqueous and anhydrous gels, ointments). These formulation examples are evaluated in skin permeation studies with model drugs, such as lidocaine, beta-methasone dipropionate (BDP), or caffeine.

As part of its extended history in the health care industry, Dow Corning has worked to provide its customers not only with high quality silicone materials, but also applications that capitalize on a broad range of material properties and potential applications.

In the case of topical applications, drug formulation development

¹ International Conference on Harmonization (ICH) Q3D Guideline for Elemental Impurities: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3D/Q3D_Step_4.pdf

goes hand in hand with progress in the technology of silicone materials. A component of that approach focuses on achieving not only the required delivery rate of active ingredients, but also reliable performance of inactive components, resulting in sensory characteristics suitable for patient use. Taken together, these factors help promote patient compliance—and greater likelihood that treatments will be successful.

Drug delivery systems that can effectively and efficiently utilize the loaded drug are generally desired. For example, pain management treatments that provide a burst effect for an early onset of patient relief are preferable. As an example of this concept, Dow Corning has developed a prototype semi-solid formulation based on a new cross-linked silicone polymer network. It delivers ibuprofen more effectively than the commercial hydro-alcoholic gel benchmark² available in Europe; more ibuprofen is delivered for a longer time. This delivery pattern is known as “spring and parachute” or “burst and delayed.” It not only shows modified delivery effects such as an initial burst, but also delayed delivery of the active, as demonstrated in flux studies through human cadaver epidermis (Figure 3).³

2 The commercial benchmark was a hydroalcoholic gel product with the following composition: isopropyl alcohol, solketal, poloxamer 406, miglyol 812, water, lavender oil, neroli oil and ibuprofen (5%). The anhydrous, silicone-based formulation was based on a novel, cross-linked silicone polymer network swollen in isododecane. The other ingredients were isopropyl alcohol, propylene glycol, oleic acid and ibuprofen (5%).

Figure 3. In vitro ibuprofen penetration profile based on a new cross-linked silicone polymer network

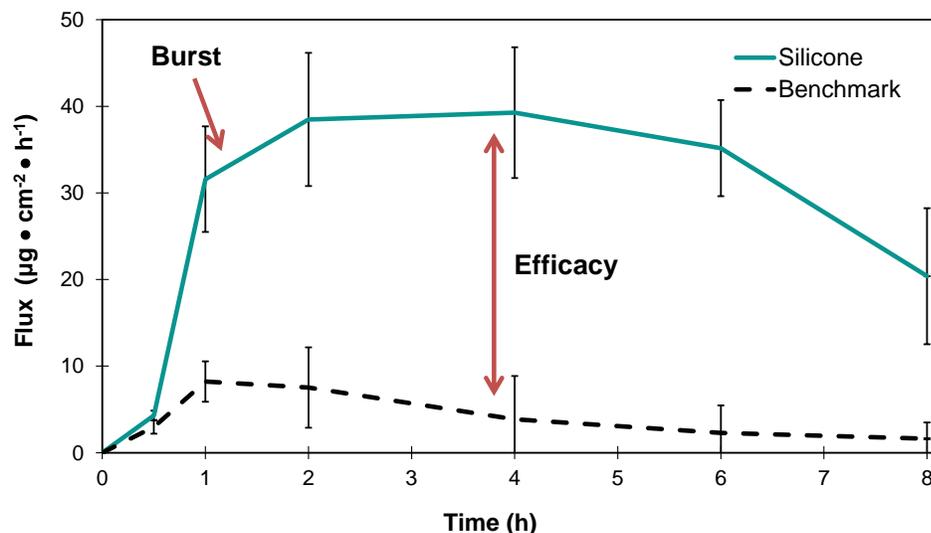


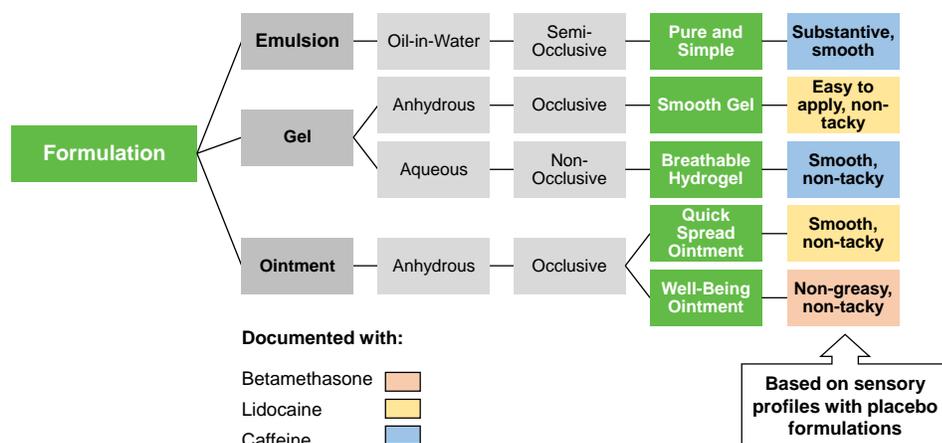
Figure 4 illustrates typical delivery forms associated with Dow Corning’s Pharmaceutical Excipient product line, as well as prototype formulations (shown in green) developed to demonstrate how particular APIs can be formulated. Sensory characteristics are described for each formulation, and the legend indicates three

APIs that were evaluated for successful delivery.

Formulation 1, **Well-Being Ointment (Dow Corning reference CPF 1838)** is medicated with BDP (betamethasone dipropionate), a corticosteroid with anti-inflammatory and immunosuppressive activities used in topical products designed to treat itching in chronic skin disorders such as eczema and psoriasis.

3 Aliyar, H.; Huber, R.; Loubert, G.; Schalau II, G. J. Efficient ibuprofen delivery from anhydrous semisolid formulation based on a novel cross-linked silicone polymer network: an in vitro and in vivo study. *J. Pharm. Sci.*, 103, 2005-2011 (2014)

Figure 4. APIs and sensory characteristics evaluated with several formulations based on silicone pharmaceutical excipients



Formulation 1: *Well-Being Ointment*

Product	Chemical Description	No BDP Wt%	With BDP Wt %
Phase A			
Dow Corning® Q7-9120 Silicone Fluid, 20 cSt	Dimethicone	15	15
Betamethasone dipropionate	Corticosteroid	--	0.064
Phase B			
Dow Corning® Silky Wax 10	Stearoxytrimethylsilane (and) Stearyl alcohol	15	15
White petrolatum jelly	Microcrystalline wax (and) Paraffin oil (and) Paraffin	70	69.936

This prototype ointment was developed to demonstrate the effectiveness of silicone-based formulations to deliver BDP with a skin penetration profile similar to a commercial benchmark,⁴ while exhibiting a better sensory profile that may help patients be more compliant with their treatment.

As Figure 5 shows, the delivery of BDP is similar to that of the benchmark, which supports the bioequivalence claim.

4 The commercial benchmark contained liquid paraffin, white soft paraffin, and 0.5 mg BDP per gram of product.

From a sensory profile standpoint, the *Well-Being Ointment* shows significant better absorbency of the ointment on the skin surface, less tackiness, less greasiness and film residue that are considered by patients as advantages versus their existing treatment (Figure 6). For this sensory evaluation, the commercial benchmark is a placebo formulation without BDP.⁵

5 The commercial benchmark placebo comprised liquid paraffin and white soft paraffin.

Figure 5. Penetration rates of BDP through epidermis piglet skin

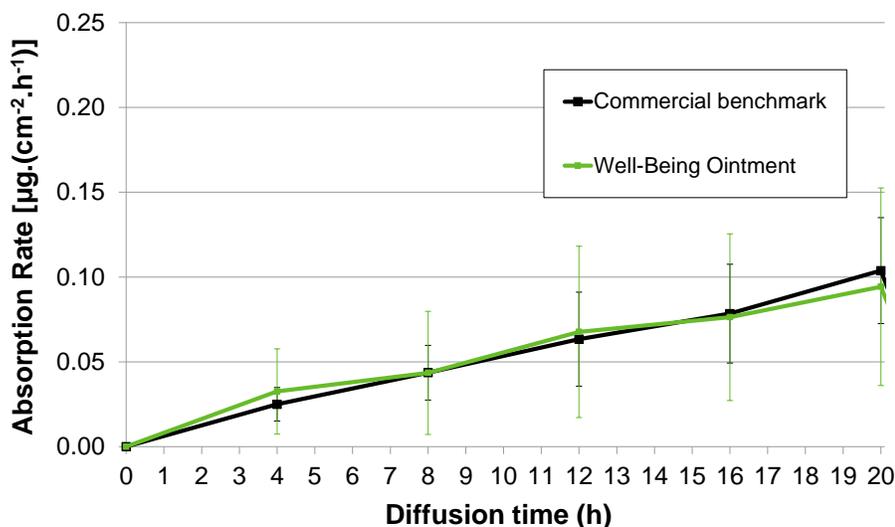
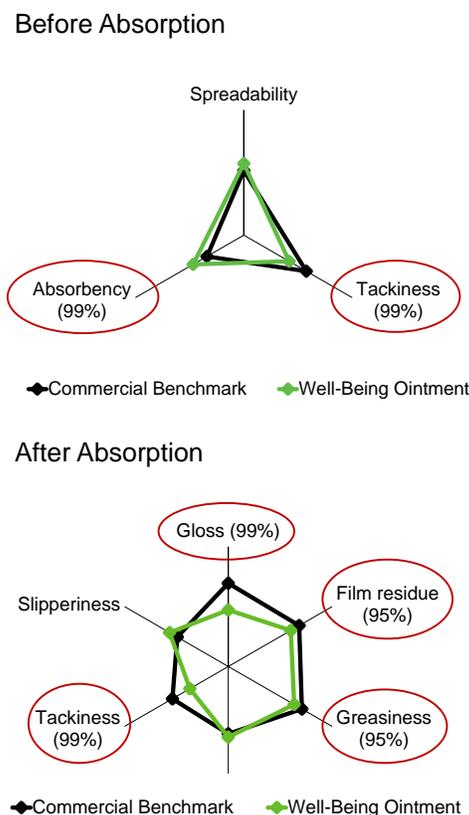


Figure 6. Sensory characteristics of *Well-Being Ointment*, before and after absorption on the skin surface

(Numbers in parentheses indicate level of confidence.)



Dow Corning Formulation Expertise in Topical Consumer Health Care Applications

Formulating for consumer health care applications is somewhat different. Formulations do not necessarily contain an active, and the physicochemical characteristics of the formulations are key. Emulsions, ointments or gels, both in aqueous or non-aqueous forms, are available as formulation examples, as shown in Figure 7.

Three prototype formulations described here, among several others mentioned in Figure 7, are available from Dow Corning. Composition and preparation details provided here illustrate various critical attributes delivered by silicone-based topical formulations, such as stabilization of actives sensitive to degradation, use of a skin protectant, and hydration.

Formulation 2, *Depigmenting Anhydrous Gel* (Dow Corning reference CPF 2017) represents an anhydrous gel designed to stabilize ascorbic acid, a com-

Formulation 2: *Depigmenting Anhydrous Gel*

Product	Chemical Description	Wt %
Phase A		
<i>Dow Corning</i> ® TI-6021 W/O Formulation Aid	PEG-10 Dimethicone	5.5
<i>Dow Corning</i> ® TI-2021 AMS Specialty Fluid	Caprylyl Methicone	9.0
<i>Dow Corning</i> ® TI-3021 Silicone Elastomer Blend	Dimethicone (and) Dimethicone Crosspolymer	22.5
DL- α -Tocopherol acetate	DL- α -Tocopherol acetate	1.0
Phase B		
Glycerin	Glycerin	57.0
L-Ascorbic acid	L-Ascorbic acid	5.0

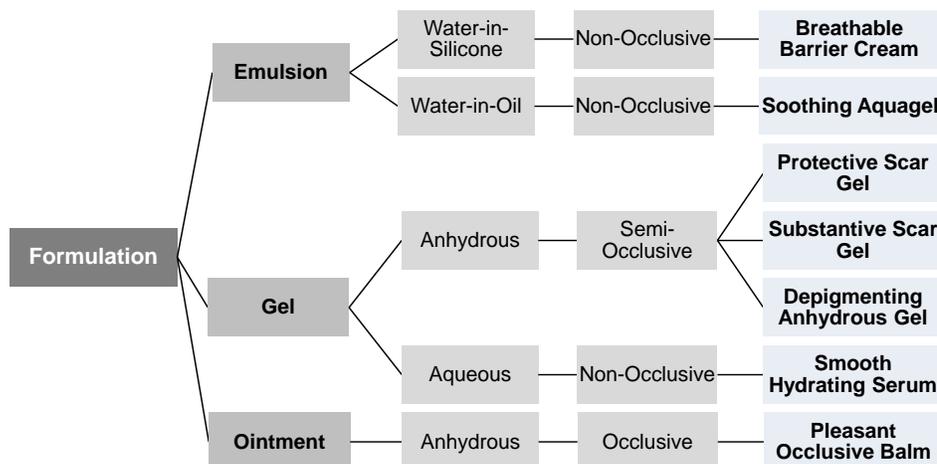
pound with antioxidant properties often used in skin depigmenting applications to treat hyperpigmentation disorders such as melasma, lentigines and post-inflammatory hyperpigmentation. However, this active is highly vulnerable to oxidation and is often replaced by ascorbic acid derivatives, thus impacting treatment efficacy and formulation cost.

This formulation illustrates how a cross-linked silicone polymer (*Dow Corning* TI-3021 Silicone Elastomer Blend) and a silicone emulsifier (*Dow Corning* TI-6021

W/O Formulation Aid) can be combined to form an anhydrous glycerin-in-silicone system that enhances ascorbic acid stabilization when compared to a commercial benchmark.⁶ Preservation of the drug's stability was shown to have a direct impact on its depigmenting activity. From a sensory profile standpoint, the gel is quickly absorbed under light rubbing.

Comparing the topical anhydrous Formulation 2 with the commercial benchmark topical formulation, both containing 5% ascorbic acid, demonstrated rapid oxidation of ascorbic acid in the commercial product. As highlighted in Figure 8, after 28 days, samples of the commercial benchmark held at both room temperature and at 50°C showed significant evidence of discoloration associated with oxidation of the drug.

Figure 7. Silicone-based topical product forms can be formulated as emulsions, gels and ointments and in various chemical systems such as water-in-silicone, water-in-oil, anhydrous and aqueous



⁶ The commercial benchmark was a solution of L-ascorbic acid in glycerol at pH 6.0, emulsified in a silicone base and prepared under nitrogen atmosphere. It has the following ingredients: water, glycerin, cyclopentasiloxane, ascorbic acid, propylene glycol, nylon-12, sodium hydroxide, citric acid, PEG/PPG-18/18 dimethicone, propylparaben, acrylates copolymer, fragrance disodium EDTA, and methylparaben.

Figure 8. Visual stability of ascorbic acid in the anhydrous silicone system after storage



Figure 9 illustrates the skin depigmenting efficiency of the anhydrous silicone system with a blend of glycerin and ascorbic acid, and the commercial benchmark, each test material containing 5% ascorbic acid. In addition, the test materials included a positive control.⁷ Skin depigmenting efficacy was assessed by measuring the reduction in melanin synthesis following the topical application of the test formulations on human epidermal tissues (RHEm) reconstituted in vitro from both keratinocytes and melanocytes. The study first confirmed that ascorbic acid is a strong depigmenting agent as shown by the large inhibition of melanin synthesis (47% inhibition of synthesis) obtained when a pure blend of glycerin and ascorbic acid is topically applied on RHEm. Although glycerin is responsible for the improved chemical stability of ascorbic acid and does not prevent both the release and penetration of ascorbic acid in skin, a pure blend of glycerin and ascorbic acid does

not represent a suitable delivery system for topical application. Indeed, a very high level of glycerin has a detrimental effect on the sensory attributes of a formulation, leading to low patient compliance and interruption of the treatment. In addition, successive application of a topical treatment containing very high level of glycerin could ultimately alter the architecture of the stratum corneum and as a result the barrier function of the skin.

As demonstrated above, the incorporation of ascorbic acid into a glycerin-in-silicone system preserves its chemical stability.

Compared to a pure blend of glycerin and ascorbic acid, the anhydrous silicone system offers significantly improved sensory characteristics.

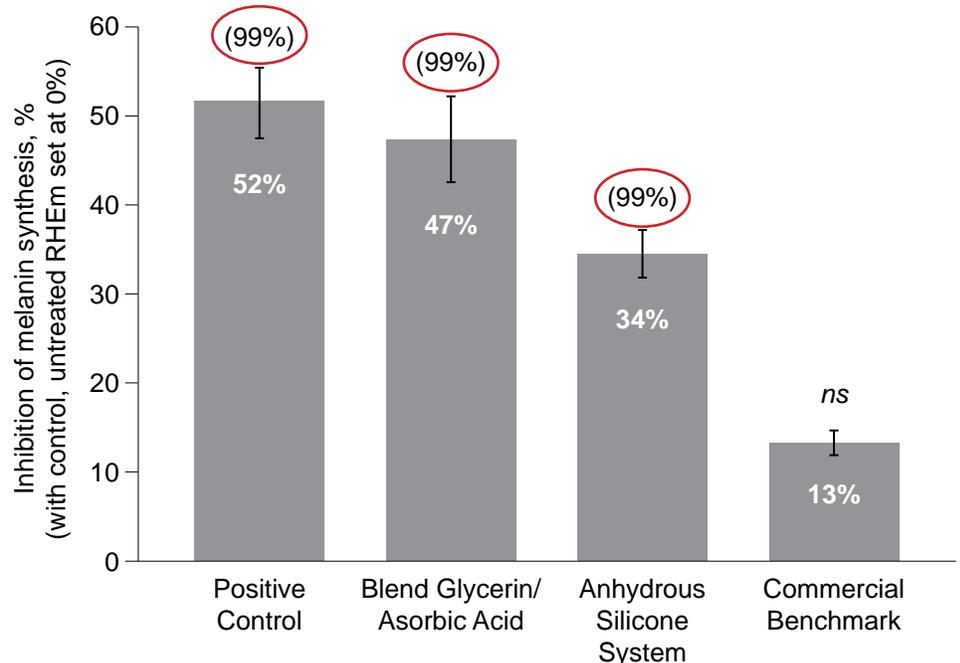
From an efficacy standpoint, as illustrated in Figure 9, the silicone-based system does not prevent the release of ascorbic acid and leads to a significant decrease in melanin synthesis (34% inhibition of synthesis), unlike the commercial benchmark which marginally (13%) impacts the melanin synthesis. In the positive control, the 4-n-butyl resorcinol serves as a highly effective tyrosinase inhibitor for the topical treatment of hyperpigmentation, exceeding by far the potency of very common skin-whitening agents such as hydroquinone, arbutin and kojic acid.⁸

In another example of a gel, Formulation 3, *Protective Scar*

⁸ <http://www.ncbi.nlm.nih.gov/pubmed/23205541>

Figure 9. Comparison of the skin depigmenting efficiency of the anhydrous silicone system with a glycerin/ascorbic acid blend, a positive control and a commercial benchmark

(Numbers in parentheses indicate level of confidence; ns indicates not significant.)



⁷ The positive control contained water, glycerin, butylene glycol, squalane, *Simmondsia chinensis*, alcohol, petrolatum, cetyl alcohol, 4-butylresorcinol, glyceryl oleate, carbomer, acrylates/C10-30 crosspolymer, alkyl acrylate, polymethyl sodium, xanthan gum, glyceryl stearate, tocopherol, sucrose stearate, potassium hydroxide, methylparaben, and propylparaben.

Gel (Dow Corning reference CPF 1688) was designed to protect healing skin. It comprises a blend of silicone fluids, a cross-linked silicone polymer and a silicone resin. One of the fluids, *Dow Corning*[®] Q7-9120 Silicone Fluid, 12,500 cSt, is part of the *Dow Corning* topical excipient product line. Because the product is manufactured to meet excipient GMP requirements and the viscosity of the fluid is within the USP Dimethicone NF monograph viscosity limits, this formulation meets the requirements for marketing as a skin protectant for OTC human drug products, according to the FDA monograph, 21CFR, part 347.10. This monograph specifies a dimethicone viscosity between 20 cSt and 30,000 cSt.

The substantive, semi-occlusive gel properties of Formulation 3 allow the product to be easily applied and spread on the skin with a pleasant after-feel and low tack.

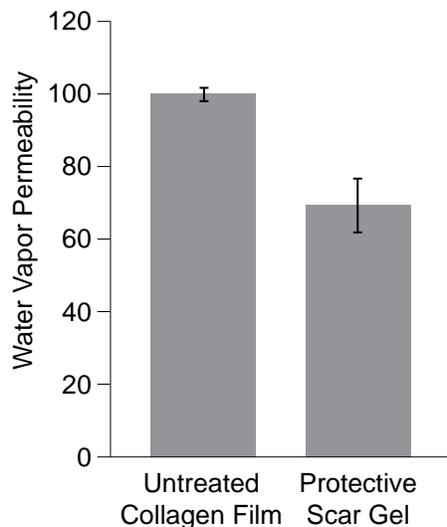
The formulation also is more substantive on skin than a commercial benchmark⁹ (Figure 10).

Figure 10 shows that while providing substantivity and skin protectant properties, the scar gel

⁹ The commercial benchmark contained polysiloxane and siloxane dioxide.

Figure 10. Water vapor permeability of the Protective Scar Gel (12.5 µm layer) as measured by Payne Cup

The water vapor permeability of the untreated, non-occlusive collagen membrane is fixed at 100%.



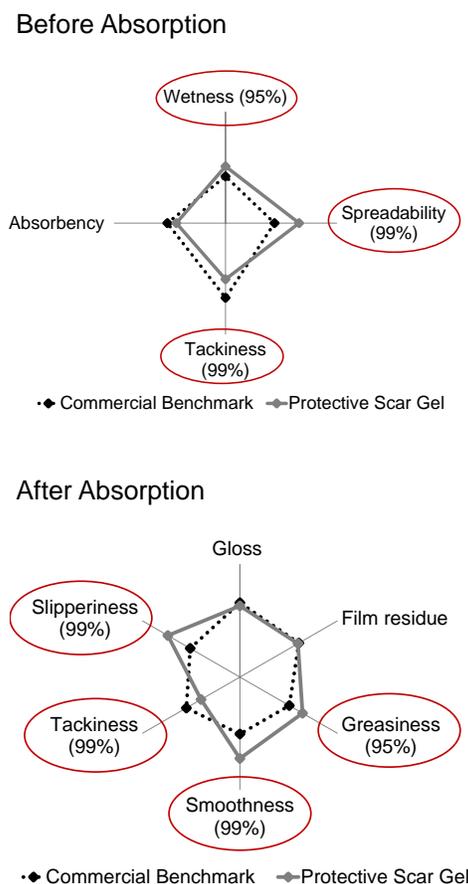
formulation is only semi-occlusive and thus allows the skin to breathe.

As shown in Figure 11, the scar gel spreads easily on the skin and is less tacky before absorption. After absorption, the scar gel has an improved slipperiness, and a smoother and less tacky feel.

Formulation 4 illustrates yet another product form. ***Soothing Aquagel (Dow Corning reference CPF 1802)***, a water-in-silicone

Figure 11. Sensory properties of the Protective Scar Gel before and after absorption

(Numbers in parentheses indicate level of confidence.)



emulsion, is a cream designed for treating keratosis-prone skin. The non-occlusive formulation has an excellent sensory profile and gives a perception of smoothness while it hydrates the skin. Salicylic acid acts as a keratolytic agent, while the urea functions as a moisturizing agent.

Formulation 3: Protective Scar Gel

Product	Chemical Description	Wt %
<i>Dow Corning</i> [®] TI-1050 Fluid, 100,000 cSt	Dimethicone	15
<i>Dow Corning</i> [®] Q7-9120 Silicone Fluid, 12,500 cSt	Dimethicone	15
<i>Dow Corning</i> [®] TI-3021 Silicone Elastomer Blend	Dimethicone (and) Dimethicone Crosspolymer	50
<i>Dow Corning</i> [®] TI-7021 Silicone Resin Blend	Dimethicone (and) Trimethylsiloxy silicate	20

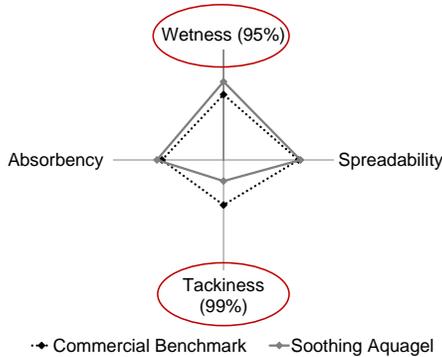
Formulation 4: Soothing Aquagel

Product	Chemical Description	Wt %
Phase A		
Dow Corning® TI-6021 W/O Formulation Aid	PEG-10 Dimethicone	2
Dow Corning® TI-1050 Fluid, 10 cSt	Dimethicone	15
Dow Corning® TI-3021 Silicone Elastomer Blend	Dimethicone (and) Dimethicone Crosspolymer	5
Phase B		
Water	Aqua	56
Urea	Urea	8
Euxyl® PE 9010	Phenoxyethanol (and) Ethylhexylglycerin	1
Phase C		
Propylene glycol	Propylene glycol	10
Salicylic acid	Salicylic acid	2

Figure 12. Sensory characteristics of the Soothing Aquagel before and after absorption

(Numbers in parentheses indicate level of confidence.)

Before Absorption



After Absorption

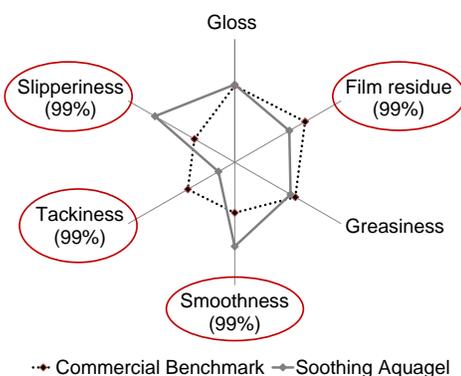


Figure 12 summarizes sensory profile results. Before absorption, the *Soothing Aquagel* cream shows significantly less tackiness when compared to the commercial benchmark.¹⁰ After absorption, the cream is less tacky and displays less residue on the skin, while providing a sensation of greater slipperiness and better smoothness.

Figure 13 illustrates surface hydration of the skin, comparing the *Soothing Aquagel* to untreated skin. After four hours, skin treated with the *Soothing Aquagel* shows significantly greater hydration than untreated skin.

This hydrating effect is complemented by the non-occlusive characteristics of the formulation *Soothing Aquagel* to provide a topical treatment for keratosis-prone

¹⁰ The commercial benchmark contained water, urea, propylene glycol, mineral oil, cyclomethicone, polyacrylate-13, triethanolamine, *Prunus amygdalus dulcis* (sweet almond) oil (*Prunus amygdalus dulcis* oil), salicylic acid, polyisobutene, lactic acid, phenoxyethanol, PEG/PPG-18/18 dimethicone, polysorbate 20, sorbitan isostearate, and tocopheryl acetate.

Figure 13. Surface hydration of the skin from Soothing Aquagel

(Numbers in parentheses indicate level of confidence.)

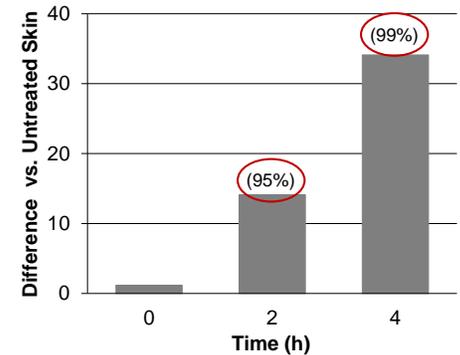
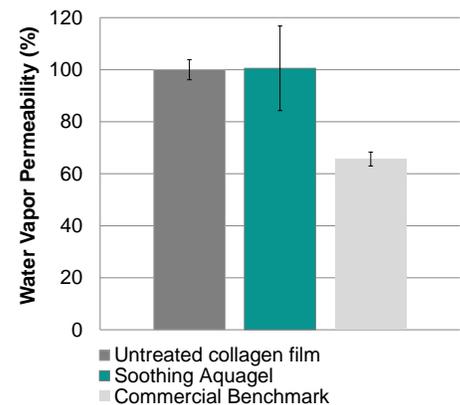


Figure 14. Water vapor permeability of Soothing Aquagel measured by Payne cup (<12.5 μm layer)

Water vapor permeability of the untreated collagen membrane is fixed at 100%.



skin, with skin breathability, compared to a commercial benchmark (Figure 14).

To further aid selection and formulation with its topical ingredients and pharmaceutical excipients, Dow Corning provides an expanding series of prototype formulations for various product forms (e.g., gels, ointments and emulsions). This collection, called “Formulating with Fascinating Silicone,” is available as a boxed set (Figure 15) or via an online application tool.



Figure 15. An expanding collection of formulations using Dow Corning® brand Topical Ingredient and Topical Pharmaceutical Excipient products is available by contacting a Dow Corning representative.



Scan the code to access the online formulation tool.

Conclusions

Given today's changing regulatory landscape, developers of topical products are challenged to seek materials that not only perform as expected, but that meet increasingly stringent safety and production requirements. With their specialized needs on the continuum from consumer products, through OTC applications, to more highly regulated pharmaceuticals, product developers

must consider more carefully the selection of appropriate materials to fit the needs of their market and application.

Based on Dow Corning's long history of providing silicones to the health care industry and its strong product development and formulating expertise, the new topical ingredient product line fully complements the existing range of topical pharmaceutical excipients. With the added benefits of tailored regulatory documentation and production targeted to the market continuum, developers of topical applications can trust that they will make the proper material selection for their needs.

For Further Reading

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