PHARMACEUTICALS/NUTRACEUTICALS & ANIMAL HEALTH

FORMULATING LASTING PARTNERSHIPS

PRODUCTS DESIGNED FOR HEALTH

The Penreco® line of petrolatums and mineral oils are used in numerous, pharmaceutical and OTC applications. Our portfolio of 500+ products includes seven white oil USP/NF grade APIs and 29 petrolatum USP grade APIs. With one of the largest portfolios of registered active pharmaceutical ingredients in the US, we continue to develop innovative solutions with our Versagel® and Versastique™ product lines. Pharmaceutical products are available in a variety of formats such as drops, creams, gels, roll-ons, sticks and sprays.

APPLICATIONS

- Skin protectant
- Topical analgesics/pain relief
- Dermatological treatments
- Ophthalmic care
- Therapeutic ointments & creams
- Medical preparation and post-surgery treatments
- Wound care: bandages/scar management
- Oral suspension formulation
- Pill coatings, gel capsules & taste masking agents
- Animal health/vaccines/adjuvants

For more than 100 years, Penreco has specialized in niche product blending to meet customer or monograph specific requirements (including, but not limited to USP/NF, EP, JP, EU, BP). We are proud to offer safe stable products from an FDA registered manufacturing site with a two-tiered system to manufacture under cGMP conditions and extensive purity and quality testing. Additionally, we have an upgraded filtering system that enables 5-micron particulate extraction.

penreco®

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To request a sample, visit penreco.com.

PETROLATUMS

CUSTOMIZED FROM START TO FINISH

Petrolatum has been around since 1872 and is a common ingredient used in formulations because it is odorless, tasteless, and compatible with the majority of APIs. Petrolatum can be either an active ingredient or an excipient. An excipient is the non-active ingredient in the formulation. It may also be referred to as the "carrier" or "vehicle" for the active ingredient since it may comprise 95% or more of the total formulation. But petrolatum can also be considered as the active ingredient in over-the-counter (OTC) drugs. Petrolatum, along with other ingredients, was listed by the FDA in a 1983 publication in the Federal Register called the Tentative Final Monograph for Skin Protectants. This made it possible for any formulation containing 30% to 100% petrolatum to make the label claim of a skin protectant. Such products are OTC drugs and therefore are regulated by the FDA.

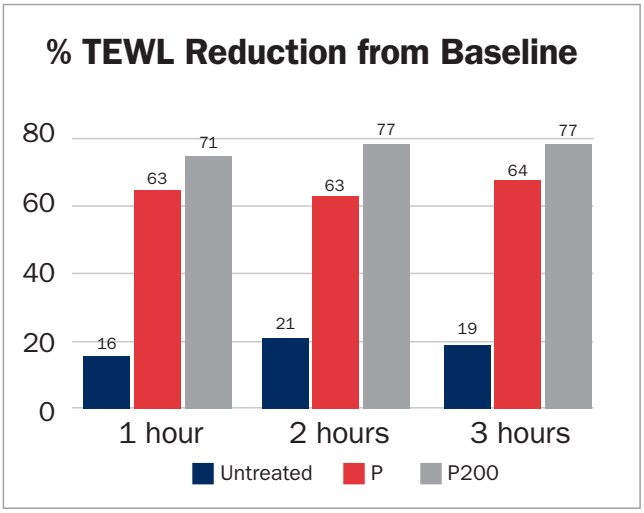
A few examples of petrolatum use include skin cream treatments for acne and psoriasis and a nonsteroidal topical medication for dermatitis. It is often used in post-surgery healing wound care as a skin protectant. Petrolatum is also an effective excipient for antibiotics to treat skin infections and stop the growth of bacteria with APIs such as zinc, bacitracin, neomycin and polymixin b.

TYPICAL PROPERTIES

	Melting Point, °F (°C) USP/ASTM D127	Viscosity SUS @ 210 °F ASTM D2161	Maximum Lovibond Color 2" Cell IP17	Consistency @ 77 °F USP/ASTM D937
WHITE PETROLATUM USP				
Ultima	130/140 (54/60)	60/75	0.5Y	155/180
Super	125/135 (52/57)	60/75	0.5Y	170/205
Snow	125/135 (52/57)	64/75	2.0Y	170/205
Regent	118/130 (48/54)	57/70	2.0Y	210/240
Lily	125/135 (52/57)	64/75	8.0Y 0.5R	170/205
Cream	125/135 (52/57)	64/75	18.0Y 1.5R	175/205
PETROLATUM USP				
Royal	118/130 (48/54)	57/70	35.0Y 3.0R	210/240
Blond	125/135 (52/57)	68/82	35.0Y 2.0R	175/205
Amber	125/135 (52/57)	68/82	35.0Y 7.0R	175/205
OINTMENT BASES WHITE PETROLATUM, USP				
Ointment Base No. 4	118/125 (48/52)	45/65	1.5Y	250/275
Ointment Base No. 6	122/133 (50/56)	60/70	1.5Y	195/230
Ointment Base No. 8	118/127 (48/53)	55/65	1.5Y	220/250

PETROLATUM AND VERSAGEL® P200 SKIN BARRIER REPAIR STUDY

A clinical study was conducted using petrolatum and Versagel P on the volar forearms of test subjects with self-perceived dry skin. TEWL measurements (DermaLab) were taken at baseline 1 hour, 2 hours, and 3 hours with re-application after each test. The study showed that petrolatum had over 60% decrease in Transepidermal Water Loss (TEWL) and Versagel P200 (gelled Petrolatum) had even higher TEWL at over 70% and both were much more efficacious than the untreated site. Thus, proving that petrolatum and Versagel P200 are highly effective moisturizing ingredients for use in therapeutic ointments and creams.



WHITE OILS

TRUSTED SECURE SOLUTIONS

In pharmaceuticals, white oils are used as a release agent, binder, carrier, and lubricants in or on tablets and capsules. Other applications include containing concentrates such as gelatin capsules, lubricating agent, and as a base material in variety of preparations such as various balms and salves. These wide-ranging uses are enabled by its non-reacting, non-polar and non-toxic properties. White oils are often preferred as they are hydrophobic, non-comedogenic, colorless, odorless, highly refined and purified, chemically and biologically stable, and do not support growth of pathogenic microorganisms.

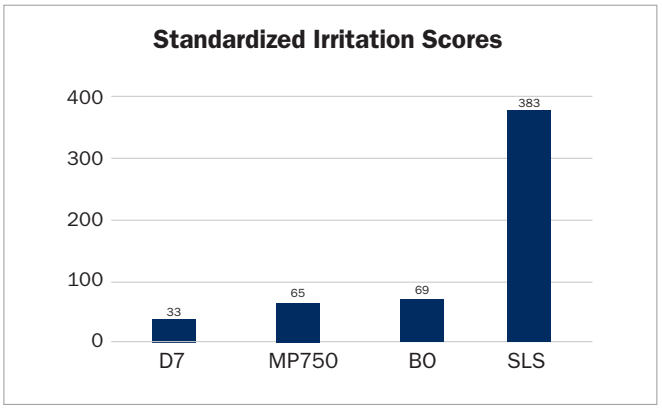
They are often used in laxatives and lubricants where the percentage of white oils may approach 100%. White oils are primarily used to treat constipation and encopresis because of its lubricating properties and tolerability. Drakeol® white oils of specific viscosities are refined to meet the purity specifications of the USP/NF and FDA standards.

TYPICAL PROPERTIES

	VISCOSITY		SPECIFIC GRAVITY	FLASH POINT ASTM D92 (Typical)		POUR POINT ASTM D97 (Typical)	
	ASTM D7042 SUS @ 100 °F	ASTM D7042 cSt @ 40 °C	ASTM D4052 @ 77 °F	°F	°C	°F	°C
MINERAL OIL USP							
Drakeol® 600	515/625	99.0/120.0	0.8600/0.8780	507	264	11	-12
Drakeol 350	350/370	66.7/71.2	0.8570/0.8730	469	243	5	-15
Drakeol 35	340/365	65.8/71.0	0.8640/0.8810	467	242	3	-16
Drakeol 34	370/410	72.0/79.5	0.8580/0.8720	478	248	5	-15
Drakeol 32	312/330	60.0/63.3	0.8560/0.8760	459	237	5	-15
Drakeol 21	200/215	38.4/41.5	0.8530/0.8760	439	226	5	-15
Drakeol 19	180/190	34.9/37.3	0.8520/0.8760	434	223	5	-15
LIGHT MINERAL OIL NF							
Drakeol 15	145/155	28.1/30.3	0.8500/0.8730	407	208	5	-15
Drakeol 13	125/135	24.2/26.3	0.8480/0.8670	391	199	5	-15
Drakeol 10	102/115	19.0/21.9	0.8380/0.8640	407	208	3	-16
Drakeol 10B	95/105	17.7/20.2	0.8670/0.8840	333	167	-23	-31
Drakeol 9	80/90	14.2/17.0	0.8330/0.8610	391	199	-15	-26
Drakeol 7	65/75	10.8/13.6	0.8330/0.8610	369	187	-15	-26
Drakeol 6 VR	10.0/106*	9.4/10.0	0.8340/0.8380	348	176	-15	-26
Drakeol 5	50.2/60.0	6.9/9.6	0.8180/0.8610	337	169	-20	-29
Draketex® 50	48.0/53.0	6.5/7.8	0.8200/0.8610	320	160	10	-12
Peneteck	39.5/44	3.9/5.3	0.8210/0.8370	305	152	-27	-33

MINERAL OIL AND VERSAGEL® MP STUDY TO DETERMINE COMPARATIVE MILDNESS OF INGREDIENTS

A clinical study was conducted using 100 micro liter-dosed occlusive patches of product applied to backs of subjects for 14 days. Using the Berger & Bowman Grading Score, the skin patches were evaluated and given standardized cumulative irritation scores. The study showed that Drakeol 7 (D7) was more than 50% less irritating than a commercial baby oil (BO) while Versagel MP 750 had a similarly low irritation score to BO. The study also showed the anionic surfactant sodium lauryl sulfate (SLS) which is a known skin irritant as a positive control. The BO and SLS provided benchmarks that further showed how both Drakeol 7 White Mineral Oil and Versagel MP are very mild ingredients in pharmaceutical and personal care applications and provide hydration without irritating sensitive skin.



WHITE OILS

TRUSTED SECURE SOLUTIONS

ADJUVANTS & INJECTABLES

White oils are used as adjuvants in animal vaccines and other veterinary drugs and as additives and binding agents. Adjuvants play an important role in the efficacy of vaccines as the antigens become more purified. Adjuvants must enhance the specific immune response against pathogens and improve protection. They must be safe, stable, and highly biocompatible because secondary effects can have an impact on the growth, reproduction rate, the comfort of the animal or cause blemishes on the body. Specialty grades of mineral oils are a known class of very effective adjuvants. High purity white oils with low viscosity are desirable in this application because of their exceptional mildness and emulsion stability.

Drakeol® 5 LT Mineral Oil NF and our Drakeol 6 VR LT Mineral Oil NF have desired hydrocarbon composition and their physical uniformity are rigidly controlled by sustaining unusually narrow tolerances for each significant property. This strict control also guarantees the highest degree of purity consistent with requirements for a pharmaceutical product.

TYPICAL PROPERTIES

	VISCOSITY		SPECIFIC GRAVITY	FLASH POINT ASTM D92 (Typical)		POUR POINT ASTM D97 (Typical)	
	ASTM D2161 SUS @ 100 °F	ASTM D7042 cSt @ 40 °C	ASTM D4052 @ 25/25 °C	°F	°C	°F	°C
LIGHT MINERAL OIL NF							
Drakeol 5	50/60	7.0/9.6	0.8180/0.8610	336	168	-20	-29
Drakeol 6 VR	60 (typical)	9.4/10.0	0.8340/0.8380	348	176	-22	-30

VERSAGEL® PW

INTELLIGENT PETROLATUM GEL TECHNOLOGY

Similar to the Versagel P product line, Penreco has developed Versagel PW. The product line combines highly purified USP-Grade white petrolatum with block copolymers and “silicone” wax in the formulation. The gelled formulation enhances the occlusivity naturally accompanying all petrolatum products. The “silicone” wax, which is a stearyl alcohol and stearoxytrimethylsliane mixture, is a detackifier which controls the stickiness on the substrate to which it is applied. The wax also helps with lubricity, melting point and viscosity. These products exhibit excellent thermal stability, as well as versatile chemical compatibility.

TYPICAL PROPERTIES

	VISCOSITY @ 70 °C (cPs), T-C, 10 RPM	FTIR IDENTIFICATION	COLOR ASTM D1500	APPEARANCE	FLASH POINT ASTM D92 °C	WATER CONTENT	ODOR
Versagel PW	76,740	Pass	0.5L	Opaque	413	0	Pass

VERSASTIQUE™

CLEAR STIQUE TECHNOLOGY

Our newest clear stick innovation furthers the evolution of our Versagel technology into solid stick applications. Versastique offers formulators excellent performance benefits:

- Stabilizes and protects your active ingredients
- Low moisture/low water activity
- Heat processed - Micro-filtered
- Self-preserving formulation base
- Resists growth/proliferation of microorganisms

Stick application solutions allow for consumers to have touch-free application systems that are hygienic and germ-free as possible. The Versastique line also helps by creating a film barrier on the skin to help with moisture management and API absorption in applications like scar management/skin restoration and pain relief treatments.

The Versastique product line includes gelling four substrates:
■ SQ Squalane ■ ML C12-15 Alkyl Benzoate ■ ME Hydrogenated Polyisobutene ■ M Mineral Oil

VERSASTIQUE LOW MELT

KEY TYPICAL PROPERTIES	SQ 5 T	ML 5 T	ME 5 T	M 5 T
Viscosity @ 130 °C (cPs) D2983	4.6	4.1	5.2	4.3
Specific Gravity @ 25/25 °C D4052	0.81	0.93	0.83	0.85
Flash Point ASTM D92 (°C)	220	195	145	188
Melting Point (°C) D3954	85	81	85	88
Appearance	Clear solid	Clear solid	Clear solid	Clear solid
Gardner Color	0.6	0.3	0.6	0.3
Hardness (g) typical	20	20	20	20

Viscosity @ 130 °C (cPs), SC4-18, 90 rpm, (10 rpm*)

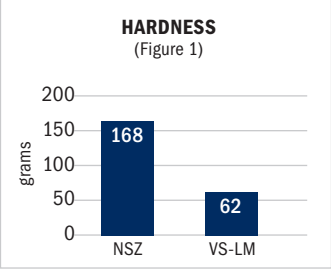
International Nomenclature of Cosmetic Ingredients (INCI)
The **Versastique Low Melt** product line includes the gelled (substrate) and Butyl Stearate, Isostearyl Alcohol, Hydrogenated Styrene/Butadiene Copolymer, Dibutyl Ethylhexanoyl Glutamide, Dibutyl Lauroyl Glutamide, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate

Texture Analysis was used to compare Versastique Scar Stick prototypes (VS & VS-Vit E) to 2 commercial scar sticks (CS & PS). VS-Vit E contained 5% Vitamin E, while both VS and VS-Vit E contained the following sunscreen ingredients avobenzone 3%, homosalate 10%, octyl salicylate 5%, and octylcrylene 4%. Texture analysis properties compared were hardness, friction and transfer rate.

Please note that only the viscosity and appearance are listed on the CoA. The remaining data are typical results that are not regularly reported on the CoA.

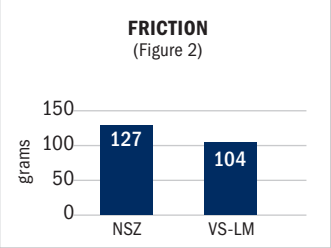
HARDNESS

Versastique prototypes have lower hardness (grams) than the wax-structured benchmark while maintaining sufficient structure and integrity. Softer stick products are gentler to apply onto the skin. (Figure 1)



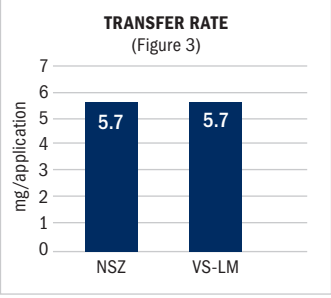
FRICTION

Versastique prototypes have lower friction (grams) than the commercial benchmark. Thus, we can conclude that the Versastique prototypes take less force to spread product over the surface. (Figure 2)



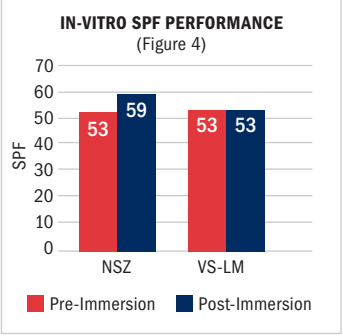
TRANSFER RATE

Versastique sunscreen prototypes have comparable or improved transfer rates (mg/application) compared to NSZ. Thus, we can conclude the amount of product being applied is equivalent or improved compared to the benchmark. This means Versastique sunscreens are gentler and easier to apply without applying excess product to the skin. (Figure 3)



EFFICACY

In-Vitro SPF Performance (static vs. post-immersion)
Versastique sunscreen prototypes have comparable SPF performance to the benchmark. The water-resistant properties of Versastique enable equivalent or higher **SPF post-immersion** vs. the **static or pre-immersion** values. The mildness, high efficiency, and water resistance properties of Versastique makes it an attractive base for high-performance mineral sunscreens. Due to the performance/formulation dynamics of mineral UV filters, it is important to optimize mineral sunscreen formulation. The incorporation or removal of one ingredient can significantly change overall product performance. (Figure 4)



RR# 2019 – 0006
RR# 2019 – 0002.
In-vitro sunscreen evaluation sample numbers: 20-088 to 20-093.

VERSAGEL®

INTELLIGENT GEL TECHNOLOGY

Penreco® has developed a unique system for thickening and gelling hydrocarbon materials. An infinite number of customized rheological properties are available — from thickened liquids to solids. The finished products are clear, colorless, hydrophobic, thermally reversible and without syneresis (oil bleed).

- Performance – excellent suspension properties and superior moisture delivery.
- Stability – stabilizes and protects active ingredients in a self-preserving formulation base.
- No harsh chemicals – milder to the skin and low toxicity.
- Does not separate or change over time.

Emollient excipients such as Versagel are used in topical formulations because of their softening and smoothening benefits on the skin. They also help the skin retain water and moisturize dry skin in addition to promoting absorption of other ingredients. They provide targeted drug delivery and non-greasy, good spreading characteristics. Specifically, Isopropyl palmitate, the substrate in our Versagel MP lines, is an established penetration enhancer for transdermal systems. Mineral Oil and Petrolatum are USP Monograph listed products giving customers a comfort level they can count on. You may already be using many of the substrates in your current formulation, but an innovative gelled option can provide better functionality or aesthetics.

TYPICAL PROPERTIES

	VISCOSITY @ 25 °C (cPs)	VISCOSITY @ 110 °C (cPs)	SPECIFIC GRAVITY @ 25 °C	SAYBOLT COLOR D-156	FLASH POINT °C ASTM D-92
VERSAGEL M (70 VIS White Mineral Oil)					
M 200	13,330 - 27,700	-	0.8421	+30	>175
M 500	47,000 - 57,000	-	0.8445	+30	>175
M 750	67,000 - 83,000	-	0.8434	+30	>175
M 1600	132,000 - 198,000	-	0.8425	+30	>175
VERSAGEL ME (Hydrogenated Polyisobutene)					
ME 500	50,000 - 75,000	-	0.8264	+30	>149
ME 750	85,000 - 110,000	-	0.8265	+30	>149
ME 1600	140,000 - 180,000	-	0.8280	+30	>149
ME 2000	245,000 -325,000	-	0.8269	+30	>149
VERSAGEL P (Petrolatum)					
P 100	-	382	0.8649	Opaque (Lovibond <3.0y)	>249
P 200	-	4,619	0.8650	Opaque (Lovibond <2.0y)	>249
VERSAGEL MC (Isohexadecane)					
MC 750	35,000 - 53,000	-	0.7856	+30	>95
MC 1600	50,000 - 70,000	-	0.79 83	+29	>95
VERSAGEL MN (Isononyl Isononanoate)					
MN 750	155,000	-	0.8540	+28	>149
MN 1600	265,000 - 339,000	-	0.8549	+29	>149
VERSAGEL MP (Isopropyl Palmitate)					
MP 750	82,000 - 108,000	-	0.8520	+30	>160
MP 1600	160,000 - 200,000	-	0.8520	+28	>160

International Nomenclature of Cosmetic Ingredients (INCI):
Each product line includes the gelled (substrate) and Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer

Our Versagel M series has been used as an active ingredient carrier in ophthalmic therapeutic drops

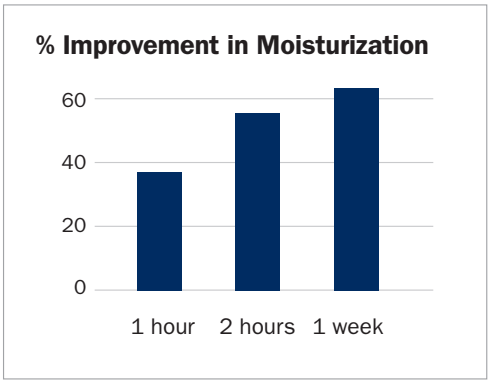
- Patents: US 9592246 (March 2017) & US 20170182071 (June 2017) - disclose improved API stabilization and suspension in Versagel
- Drug Master Filing (DMF) #034622 - will cover the chemistry, manufacturing and quality of Versagel pharmaceutical excipients

The Versagel products are not USP/NF monograph listed however some substrates have the approvals, and the polymer system is used in medical device applications. If you are interested in working with a Versagel in your next formulation, please contact us for support.

VERSAGEL ME750 MOISTURIZATION AND LIP CONDITIONING BENEFITS STUDY

In the clinical study, moisture content of the lips was measured with a NOVA Dermal Phase Meter (NOVA DPM) which measures the moisture in the skin by measuring an electrical parameter (impedance). Overall, there was a 61% improvement in lip moisture content in 1 week.

The high sensitivity of lip skin is well known and partly due to its much lower number of skin layers compared to regular skin. This makes lips highly susceptible to dryness. The excellent performance of Versagel ME in lip care applications is due to its exceptional mildness, moisturization, and lip conditioning benefits—which also makes it an excellent excipient for APIs like lysine in cold sore treatments.



CERTIFICATIONS & REGULATORY INFORMATION

REGULATORY INFORMATION

- White Mineral Oil and Petrolatums are included on the TSCA Inventory.
- The CAS number for all white oils is 8042-47-5 and petrolatum products is 8009-03-8.
- See Safety Data sheet for additional health, safety and disposal information.
- All Penreco USP petrolatums meet the following FDA regulations: 21 C.F.R. § 172.880 regarding direct food additives, 21 C.F.R. § 178.3700 regarding indirect food additives, and 21 C.F.R. § 573.720 regarding animal food additives.
- All Drakeol® products, Draketex® 50, and Peneteck meet the following FDA regulations: 21 C.F.R. § 172.878 regarding direct food additives, 21 C.F.R. § 178.3620 (a) regarding indirect food additives, and 21 C.F.R. § 573.680 regarding animal food additives and H1 food processing lubricant standards.

WHITE OILS

- Complies with all USP/NF specifications and yields emulsified injections of suitable fluidity.
- Extraordinary purity due to the high temperature manufacturing process, no water is added into the process thus ensuring no microbial growth.
- Manufactured to meet and surpass the purity requirements of the Pharmacopoeias.
- Kosher and Halal certified.
- Used for emulsions and inverse emulsions.
- All Drakeol products are inhibited with less than 20 ppm dl-alpha tocopherol (Vitamin E).
- Colors for all Drakeol products are +30 Saybolt.
- Test methods used are current USP/ASTM or validated Penreco equivalents.

OUR COMMITMENT

Customer Engagement

Foster key values to our customers: understand expectations, provide clear communication, always listening and improving.

Exceeding Industry Standards

Formulate and execute strategic action plans based on specific areas of customer need, safely delivering products with the highest quality and integrity.

Transparency in Communication

Putting plans into action. Our goal is to exceed your expectations, provide continuity of supply with on time and full deliveries so you have confidence in your product planning.

penreco®

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