## 🗧 | HEALTH

# Topical Drug Delivery

## Excipients for creams, gels, and lotions

Stable and efficient semisolid preparations with optimal skin-feel have become the desirable standard in topical and transdermal drug delivery. Lubrizol Life Science Health (LLS Health) has long-standing experience with semisolids, offering rheology-modifying, emulsifying and bioadhesive excipients.

Our **Carbopol® polymers, Pemulen™ polymers, and Noveon® polycarbophil** have been used extensively for more than fifty years in both prescription and over-the-counter topical drug products.

**Topical Applications** - All polymers listed in the chart below are suitable for use in topical applications and are present in commercialized topical products. Topical applications can include creams, lotions, gels, and ointments for dermal, vaginal, and rectal use, among others.

Pharmacopeia Monograph Compendial Name					Application Type				Viscosity Specification Ranges			
Product Trade Name	Polymerization Solvent	United States (USP/NF)	Europe (Ph.Eur.)/ India (I.P.)	Japan (JPE) <sup>1</sup>	China (Ch.P.)	Lotions	Creams	Gels	Bio- adhesives	% w/w	Minimum (Cp)	Maximum (Cp)
Carbopol	» polymers											
971P NF	Ethyl Acetate	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	٠	-	•	0.5	4,000	11,000
974P NF	Ethyl Acetate	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	٠	•	•	0.5	29,400	39,400
980 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type C	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	-	٠	•	•	0.5	40,000	60,000
981 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	٠	-	•	0.5	4,000	10,000
5984 EP	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	٠	•	•	0.5	30,500	39,400
ETD 2020 NF	Cosolvent <sup>2</sup>	Carbomer Interpolymer Type B				•	٠	•	•	1.0	47,000	77,000
Ultrez 10 NF	Cosolvent <sup>2</sup>	Carbomer Interpolymer Type A				•	٠	•	•	0.5	45,000	65,000
Pemulen™	polymers											
TR-1 NF	Cosolvent <sup>2</sup>	Carbomer Copolymer Type B				•	٠	•	•	1.0	14,000	26,500
TR-2 NF	Cosolvent <sup>2</sup>	Carbomer Copolymer Type A				•	٠	•	•	1.0	4,500	13,500
Noveon®	polycarbophil USI	P				÷						
AA-1 USP	Ethyl Acetate	Polycarbophil				-	٠	•	•	0.2	2,000	12,000



<sup>1</sup>Based on customer request, Lubrizol certifies select lots of product against the JPE Carboxyvinyl Polymer monograph. <sup>2</sup>Cosolvent = mixture of Ethylacetate (class III solvent) and Cyclohexane (class II solvent).

### **Enabling innovation through our multifunctional excipients, which are:**

- Ideal for imparting **rheology control** in topical formulations
- Highly efficient thickeners and gel formers at low usage levels in aqueous, hydroalcoholic, and anhydrous systems

#### Typical Usage Levels of LLS Health Polymers in Topical Applications

Application	Usage Level (wt. %)				
Topical gels (aqueous, anhydrous, hydroalcoholic)	0.5 - 3.0				
Lotions, creams	0.2 - 1.0				
Topical emulsions	0.2 - 0.4				

- Able to provide stable, uniform emulsions and suspensions
- Excellent bioadhesive polymers for improving the bioavailability of some active ingredients
- Compatible with acidic, basic, and neutral drugs
- Thermally stable, allowing for versatility in manufacturing and final product sterilization
- Optimal for providing **enhanced aesthetics** and feel for the creation of non-greasy creams, exceptionally clear gels, and other semisolid formulations



Additional FDA IID Ingredients - LLS Health also offers an array of additional inactive ingredients for semisolid topicals, such as humectants, emollients, emulsifiers, and surfactant thickeners. The below ingredients are featured on the FDA's Inactive Ingredient Database (IID). Please visit our website for more information.

Additional FDA IID Ingredients* Recommended for Topical Applications								
Trade Name	Chemical Name	IID Maximum Potency - Topical**	Typical Use Level	Functionality				
Emollients								
Schercemol <sup>™</sup> DIA ester	Diisopropyl Adipate	20%	1-10%	Light emollient Solubilization, dermal penetration Hydroalcoholic, alcohol dispersible				
Schercemol <sup>™</sup> 318 ester	Isopropyl Isostearate	3%	1-10%	Medium emollient Derived-natural***				
Schercemol <sup>™</sup> OHS ester	Ethylhexyl Hydroxystearate	12%	1-10%	Medium emollient Derived-natural***				
Schercemol <sup>™</sup> OLO ester	Oleyl Oleate	2.55%	1-10%	Medium emollient Natural***				
Schercemol™ 1688 ester	Cetearyl Ethylhexanoate	3%	1-10%	Medium emollient Derived-natural***				
Glucam <sup>™</sup> P-20 distearate emollient	PPG-20 Methyl Glucose Ether Distearate	4.75%	1-10%	Light emollient Barrier for water loss, moisturization				
Solulan™ 75 (Solulan™ L-575) lanolin derivative	PEG-75 Lanolin	1.5%	1-10%	Emollient Non-ionic O/W emulsifier (HLB 15) Water, alcohol soluble (miscible)				
Vilvanolin™ L-101 Ianolin derivative	Mineral Oil (and) Lanolin Alcohol	11%	0.5-5%	Emollient Non-ionic W/O emulsifier (HLB 8)				
Emulsifiers								
Glucate <sup>™</sup> SS emulsifier	Methyl Glucose Sesquistearate	3.5%	0.5-3%	Non-ionic W/O emulsifier (HLB 6.4), co-emulsifier Structurant Derived-natural***				
Glucamate <sup>™</sup> SSE-20 emulsifier	PEG-20 Methyl Glucose Sesquistearate	3.5%	0.5-3%	Non-ionic O/W emulsifier (HLB 15.4), co-emulsifier				
Promulgen™ D nonionic emulsifier	Cetearyl Alcohol (and) Ceteareth 20	8%	1-5%	Non-ionic O/W emulsifier (HLB 12) Structurant Derived-natural***				
Promulgen™ G nonionic emulsifier	Stearyl Alcohol (and) Ceteareth 20	4%	1-5%	Non-ionic O/W emulsifier (HLB 12.5) Structurant Derived-natural***				
Humectants								
Glucam™ E-10 humectant	Methyl Gluceth-10	5%	1-5%	Humectant, tackiness reduction				
Glucam™ E-20 humectant	Methyl Gluceth-20	5%	1-5%	Humectant, tackiness reduction				

\*US Food and Drug Administration's Inactive Ingredient Database.

🕒 | HEALTH

\*\*The IID is updated quarterly. For the most current information, please refer to the FDA Inactive Ingredient Database.

\*\*\*Renewable Carbon Index (RCI) is calculated under ISO 16128. RCI = 1.00 meets the definition of natural under the ISO standard. RCI > 0.50 meets the definition of derived-natural.





# Formulating with confidence:

**Our Excipients:** 

- Are manufactured under GMPs in ISO:9001 certified facilities (applies to Carbopol<sup>®</sup> polymers, Pemulen<sup>™</sup> polymers, and Noveon<sup>®</sup> polycarbophil
- Have established DMFs

   (applies to Carbopol<sup>®</sup> polymers, Pemulen<sup>™</sup> polymers, and Noveon<sup>®</sup> polycarbophil)
- Have been extensively tested for safety

#### **Partnering for all Development Phases:**

- Worldwide technical and application support services
- Dedicated global regulatory staff and quality assurance
- Sustainable supplier owned by Berkshire Hathaway
- Decades of manufacturing and polymer expertise

#### **Driven by Consumers:**

- Improving patient lives by providing a full excipient portfolio for nearly all dosage forms
- Advancing medical innovation by progressing partner products quickly to market
- Proactively responding to ever-changing regulatory and market needs



#### Lubrizol.com/Health

G LUBRIZOL LIFE SCIENCE

9911 Brecksville Road Cleveland, OH 44141-3201 USA

The information contained herein is believed to be reliable, but no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end-product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the user. Lubrizol Advanced Materials, Inc., shall not be liable for and the customer assumes all risk and liability for any use or handling of any material beyond Lubrizol Advanced Materials, inc.'s direct control. The SELLER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Nothing contained herein is to be considered as permission, recommendation nor as an inducement to practice any patented invention without permission of the patent owner. Lubrizol Advanced Materials, Inc., is a wholly owned subsidiary of The Lubrizol Corporation.

©2020 The Lubrizol Corporation, all rights reserved. All marks are the property of The Lubrizol Corporation. The Lubrizol Corporation is a Berkshire Hathaway company.