

simplify your semi-solid formulations

High-quality pharma raw materials backed with global regulatory support



The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

**SAFC**®

Pharma & Biopharma Raw Material Solutions

## n broad product portfolio & global support

Finding the right excipient that matches your needs as well as regulatory demands can be a complicated challenge in semi-solid formulation. Our excipients for semi-solid dosage forms support rapid formulation and easy local application as well as regulatory compliance of ointments, creams, gels, suppositories, and patches.

We offer a comprehensive range of products globally. By choosing our high-quality raw materials, you will not only benefit from our Emprove® Program, but also from our regulatory know-how and global support, enabling you to bring your product to market faster and reduce regulatory risks.

#### Benefits

- High-quality pharma raw materials
- Emprove® documentation for risk assessment
- Dedicated regulatory support

## Penetration Enhancers: Urea & DMSO

To increase the bioavailability of your transdermal applications, we offer a range of high-quality products, produced in accordance with applicable GMP guidelines.

#### Urea

- The only API grade urea on the market with CEP and DMF
- Meets regulatory requirements according to ICHQ7 GMP guidelines; complies with Ph Eur, BP, and USP
- Includes microbiological and melamine testing
- Emprove® Expert grade to meet your requirements for high-risk applications

#### **DMSO**

- Complies with Ph Eur, USP and ChP and fulfills IPEC-PQG GMP guidelines
- Includes microbiological and endotoxin testing
- Emprove® Expert grade to meet your requirements for high-risk applications

# Polymers for topical & transdermal formulations: PVA & PEG

The raw materials' ability to topically deliver a wide variety of drug molecules makes them ideal carriers, helping you make the most out of your semi-solid formulations.

#### Polyvinyl alcohol

Polyvinyl alcohol (PVA) is a synthetic polymer that can be used as a major component of and matrix material for semi-solid formulations. It is typically applied in topical creams, gels, and also in transdermal patches.

Our portfolio offers a wide range of PVA grades of different viscosities, molecular weights, and degrees of hydrolysis. This way, we can provide you with a high quality product with just the right properties you need for your specific application. Additional application of PVA beyond topical and transdermal formulations include ophthalmics and oral solid dosage forms.

#### Polyethylene glycol

Polyethylene glycols (PEGs) are widely used in creams and ointments and also serve as a suppository base. PEGs are non-volatile, have an outstanding safety profile and very broad range of applications.

The consistency of semi-solid preparations can be easily defined and adjusted by mixing liquid, low molecular weight PEGs with solid or paste PEGs of a higher molecular weight. Blending PEGs in this way is supported as solid PEGs are not soluble in liquid PEGs; nevertheless, such preparations have excellent solubility and good dissolution behavior in water.

#### **Benefits**

- Broad range of PVA and PEG types for multiple application needs
- Multi-compendial material
- Emprove® Program and documentation
- Additional PVA specifications surpassing compendial requirements to support patient safety and good tolerability



Cat. No.	Article
Antioxidants	
5.00090	L(+)Ascorbyl palmitate EMPROVE® ESSENTIAL Ph Eur, BP, NF, FCC, E 304
1.06357	Sodium disulfite (sodium metabisulfite), EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF, E 223
1.06652	Sodium sulfite EMPROVE® ESSENTIAL Ph Eur, BP, NF, E 221
1.08421	Titriplex® III (ethylenedinitrilotetraacetic acid disodium salt dihydrate) EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP

Cat. No.	Article
Buffers & pH Modifiers	
1.00056	Acetic acid (glacial) 100%, EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E 260
1.00058	Acetic acid 96%, EMPROVE® ESSENTIAL
1.05422	Ammonia solution 25%, EMPROVE® ESSENTIAL Ph Eur, BP
1.00247	Citric acid anhydrous fine-granular, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, FCC, E 330
1.00241	Citric acid anhydrous powder EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, E 330, FCC
1.00242	Citric acid monohydrate crystalline, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, USP, FCC, E 330
1.00243	Citric acid monohydrate powder, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, FCC, E 330
1.00312	Hydrochloric acid 25%, EMPROVE® ESSENTIAL Ph Helv.
1.00314	Hydrochloric acid fuming 37 % EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, NF
1.00366	(S)-Lactic acid about 90%, EMPROVE® EXPERT Ph Eur, BP, E 270
1.00563	ortho-Phosphoric acid 85%, EMPROVE® ESSENTIAL Ph Eur, BP, JPE, NF, E 338
1.04956	tri-Potassium citrate monohydrate EMPROVE® ESSENTIAL Ph Eur, BP, USP, FCC, E 332
1.05101	di-Potassium hydrogen phosphate anhydrous, EMPROVE® ESSENTIAL Ph Eur, BP, E 340
1.06431	tri-Sodium citrate 5,5-hydrate EMPROVE® ESSENTIAL E 331
1.06447	tri-Sodium citrate dihydrate, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, E 331
1.06432	tri-Sodium citrate dihydrate crystalline, EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E 331
1.06446	tri-Sodium citrate dihydrate powder, EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E 331
1.06345	Sodium dihydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur, BP, ChP, USP, JPE, E 339
1.06349	Sodium dihydrogen phosphate monohydrate EMPROVE® ESSENTIAL BP, ChP, USP
1.06585	di-Sodium hydrogen phosphate anhydrous, EMPROVE® ESSENTIAL Ph Eur, BP, JPE, USP, E 339
1.06576	di-Sodium hydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur, BP, USP
1.06573	di-Sodium hydrogen phosphate dodecahydrate crystalline, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP
1.06574	di-Sodium hydrogen phosphate heptahydrate EMPROVE® ESSENTIAL DAC, USP
1.06577	tri-Sodium phosphate dodecahydrate EMPROVE® ESSENTIAL NF, E 339
1.06514	Sodium thiosulfate pentahydrate crystalline, EMPROVE® ESSENTIAL Ph Eur, BP, USP
1.00713	Sulfuric acid 95–98%, EMPROVE® ESSENTIAL Ph Eur, BP, JPE, NF
1.08307	Tris(hydroxymethyl)aminomethane (Trometamol) high purity, EMPROVE® EXPERT Ph Eur, BP, ChP, JPC, USP, ACS

Cat. No.	Article
Ingredients	
1.05006	Bole white powder, low bacterial content, for internal use, EMPROVE® ESSENTIAL Ph Eur, BP
1.05980	D-Mannitol EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, FCC, E 421
1.05988	D-Mannitol fine powder, EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, FCC, E 421
1.05995	(-)-Menthol EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP
1.08486	Urea cryst. EMPROVE® ESSENTIAL Ph Eur, BP, ChP, USP, JP

Cat. No.	Article	
Mineral Sa	Mineral Salts	
1.01084	Aluminium chloride hexahydrate EMPROVE® ESSENTIAL Ph Eur, BP, USP	
1.01867	Calcium chloride dihydrate crystalline, Ph Eur, JP, USP, FCC, E 509	
1.42002	Calcium chloride dihydrate EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP, FCC, E 509	
1.02102	Calcium lactate pentahydrate EMPROVE® ESSENTIAL Ph Eur, BP, USP, E 327	
1.37182	Magnesium sulfate heptahydrate EMPROVE® EXPERT Ph Eur, BP, JP, USP	
1.06400	Sodium chloride EMPROVE® ESSENTIAL Ph Eur, BP, USP	
1.37017	Sodium chloride EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP	
1.16224	Sodium chloride EMPROVE® EXPERT Ph Eur, BP, JP, USP	
1.04163	Sodium chloride granulated, EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP	
1.08800	Zinc acetate dihydrate EMPROVE® ESSENTIAL Ph Eur, USP	
1.28221	Zinc chloride EMPROVE® EXPERT Ph Eur, BP, USP	
1.08846	Zinc oxide EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP	
1.28209	Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP	

Cat. No.	Article	
Preservati	Preservatives	
1.37123	Benzalkonium chloride EMPROVE® EXPERT Ph Eur, NF	
1.37124	Benzalkonium chloride solution 50 % (aqueous solution), EMPROVE® EXPERT Ph Eur, NF	
1.00130	Benzoic acid powder, EMPROVE® ESSENTIAL Ph Eur, BP, USP, E 210	
1.00160	Boric acid crystalline, EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF	
1.00162	Boric acid powder, EMPROVE® ESSENTIAL Ph Eur, BP, NF	
1.08597	Hydrogen peroxide 30%, stabilized, EMPROVE® ESSENTIAL Ph Eur, BP, USP	

Cat. No.	Article	
Preservativ	Preservatives	
1.00366	(S)-Lactic acid about 90%, EMPROVE® EXPERT Ph Eur, BP, E 270	
1.05119	Potassium sorbate granules, EMPROVE® ESSENTIAL Ph Eur, BP, NF, FCC, E 202	
1.05118	Potassium sorbate powder, EMPROVE® ESSENTIAL Ph Eur, BP, ChP, NF, FCC, E 202	
1.06290	Sodium benzoate EMPROVE® ESSENTIAL Ph Eur, BP, NF, FCC, E 211	
1.06303	di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF	
1.00662	Sorbic acid EMPROVE® ESSENTIAL Ph Eur, BP, ChP, NF, FCC, E 200	
1.06757	Methyl 4-hydroxybenzoate EMPROVE® ESSENTIAL BP, Ph Eur, JP, NF	
1.06756	Methyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur, BP, NF	
1.07427	Propyl 4-hydroxybenzoate EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF	
1.07428	Propyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur, BP, NF	
8.17043	Thimerosal EMPROVE® ESSENTIAL Ph Eur, BP	

Cat. No.	Article
Solvents	
1.00989	Cetyl alcohol EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF
1.37117	Dimethyl sulfoxide EMPROVE® EXPERT Ph Eur, ChP, USP
1.00967	Ethanol 96%, EMPROVE® EXPERT Ph Eur, ChP, JP, USP
1.00971	Ethanol 96%, EMPROVE® EXPERT Ph Eur, BP, ChP
1.00986	Ethanol absolute, EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
1.00844	Ethanolamine EMPROVE® ESSENTIAL Ph Eur, BP, NF
1.00864	Ethyl acetate EMPROVE® ESSENTIAL Ph Eur, BP, NF
1.07478	1,2-Propanediol EMPROVE® EXPERT Ph Eur, BP, USP
1.00995	2-Propanol EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP
8.17066	Isopropyl myristate EMPROVE® ESSENTIAL Ph Eur, NF

Cat. No.	Article	
Surfactant	Surfactants	
1.00989	Cetyl alcohol EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF	
1.15419	Cetyl palmitate 15 (cetylesters wax) EMPROVE® ESSENTIAL Ph Eur, NF	
1.37112	Poloxamer 188 EMPROVE® EXPERT (stabilized with 70 ppm BHT), Ph Eur, NF	
8.17034	Sodium dodecyl sulfate EMPROVE® ESSENTIAL Ph Eur	
8.17072	TWEEN® 20 (Polysorbate) EMPROVE® ESSENTIAL Ph Eur, JPE, NF	
8.17076	TWEEN® 60 (Polysorbate) EMPROVE® ESSENTIAL Ph Eur, JPE, NF	
8.17061	TWEEN® 80 (Polysorbate) EMPROVE® ESSENTIAL Ph Eur, JP, NF	

Cat. No.	Article
Thickeners	
1.01615	Agar extra pure, EMPROVE® ESSENTIAL Ph Eur, BP
1.15419	Cetyl palmitate 15 (cetylesters wax) EMPROVE® ESSENTIAL Ph Eur, NF
1.04078	Gelatin powder, EMPROVE® ESSENTIAL Ph Eur, BP, NF
1.04228	Gum arabic spray-dried, EMPROVE® ESSENTIAL Ph Eur, BP
1.41350	Polyvinyl alcohol 4-88, EMPROVE® ESSENTIAL Ph Eur, ChP, JPE, USP
1.41354	Polyvinyl alcohol 5-88, EMPROVE® ESSENTIAL Ph Eur, USP, JPE
1.41351	Polyvinyl alcohol 8-88, EMPROVE® ESSENTIAL Ph Eur, USP, JPE
1.41355	Polyvinyl alcohol 18-88, EMPROVE® ESSENTIAL Ph Eur, ChP, USP, JPE
1.41352	Polyvinyl alcohol 26-88, EMPROVE® ESSENTIAL Ph Eur, USP, JPE
1.41356	Polyvinyl alcohol 28-99, EMPROVE® ESSENTIAL Ph Eur, JPE
1.41353	Polyvinyl alcohol 40-88, EMPROVE® ESSENTIAL Ph Eur, ChP, USP, JPE
8.17001	Polyethylene glycol 200 EMPROVE® ESSENTIAL DAB 8
8.17002	Polyethylene glycol 300 EMPROVE® ESSENTIAL Ph Eur
8.17003	Polyethylene glycol 400 EMPROVE® ESSENTIAL Ph Eur, JP
8.17005	Polyethylene glycol 1500 scales, EMPROVE® ESSENTIAL Ph Eur
8.17019	Polyethylene glycol 3000 EMPROVE® ESSENTIAL Ph Eur
8.17006	Polyethylene glycol 4000 powder, EMPROVE® ESSENTIAL Ph Eur
8.17007	Polyethylene glycol 6000 EMPROVE® ESSENTIAL Ph Eur
8.17018	Polyethylene glycol 20000 EMPROVE® ESSENTIAL Ph Eur
1.13126	Silicon dioxide colloidal, highly dispersed, EMPROVE® ESSENTIAL Ph Eur, JP, NF, E 551
1.11544	Wax white in pastilles EMPROVE® ESSENTIAL Ph Eur, BP

### Discover our formulation portfolio

Our broad range of GMP products covers pharmaceutical raw materials for the development and manufacture of solid, semi-solid, and liquid dosage forms for small and large molecules. Explore our functional excipients specifically developed for solubility enhancement, improved process efficiency, specific administration routes or release profiles. Benefit from high-quality products with a wide range of functionalities backed by stringent quality control and regulatory support.

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#### The Emprove® Program

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time and resource intensive. Our Emprove® Program combines high-quality products, comprehensive documentation, and superior customer support to facilitate your efforts in qualification, risk assessment, and process optimization. Choose from over 2000 dossiers covering hundreds of raw and starting materials, filter and single-use products, chromatography resins, and cell culture media.

The Emprove® Program not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. It is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:
SigmaAldrich.com/emprove

The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: **SigmaAldrich.com** 

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