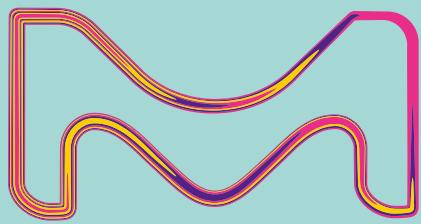


MERCK

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

A 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

For more information: SigmaAldrich.com/semisolid

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
1.06946	Oxynex® LM antioxidant for fats and oils EMPROVE® ESSENTIAL
1.08330	Oxynex® L liquid antioxidant for fats and oils EMPROVE® ESSENTIAL

Cat. No.	Article
Buffers & pH Modifiers	
1.00056	Acetic acid (glacial) 100 % EMPROVE® EXPERT 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, JP, 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
1.00802	L(+) -Tartaric acid cryst. EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, NF, E 334
1.00803	L(+) -Tartaric acid powder EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, NF, E 334

Cat. No.	Article
Ingredients	
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 Salts	
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
1.37008	Magnesium chloride hexahydrate cryst. EMPROVE® EXPERT Ph Eur, BP, USP, JPC, ACS
1.05832	Magnesium chloride hexahydrate cryst. EMPROVE® EXPERT Ph Eur, BP, USP, JPC, FCC, E 511

Cat. No.	Article
Preservatives	
1.37123	Benzalkonium chloride EMPROVE® EXPERT Ph Eur, JP, NF
1.37124	Benzalkonium chloride (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, JP, NF
1.08597	Hydrogen peroxide 30 %, stabilized EMPROVE® ESSENTIAL Ph Eur, BP, USP

Cat. No.	Article
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, ChP, NF, FCC, E 202
1.05118	Potassium sorbate powder EMPROVE® ESSENTIAL Ph Eur, BP, ChP, NF, FCC, E 202
1.06290	Sodium benzoate EMPROVE® EXPERT Ph Eur, BP, ChP, JP, 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® EXPERT Ph Eur, BP, ChP, JP, NF
1.06756	Methyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur, BP, NF
1.07427	Propyl 4-hydroxybenzoate EMPROVE® EXPERT Ph Eur, BP, ChP, JP, NF
1.07428	Propyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur, BP, NF
8.17043	Thimerosal EMPROVE® ESSENTIAL Ph Eur, BP
1.00981	Benzyl alcohol EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF
1.00987	Benzyl alcohol EMPROVE® EXPERT Ph Eur, BP, JP, NF
1.37120	Benzyl Alcohol EMPROVE® EXPERT Ph Eur, ChP, JP, NF
1.01806	Benzyl benzoate EMPROVE® EXPERT Ph Eur, BP, USP

Cat. No.	Article
Solvents	
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
Surfactants	
1.00989	Cetyl alcohol EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF
1.15419	Cetyl palmitate 15 (cetyl esters 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
Viscosity Modifiers	
1.15419	Cetyl palmitate 15 (cetylestesters 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, NF
8.17002	Polyethylene glycol 300 EMPROVE® EXPERT Ph Eur, NF
8.17003	Polyethylene glycol 400 EMPROVE® EXPERT Ph Eur, JP, NF
8.17005	Polyethylene glycol 1500 scales EMPROVE® ESSENTIAL Ph Eur, NF
8.17019	Polyethylene glycol 3000 EMPROVE® ESSENTIAL Ph Eur, NF
8.17006	Polyethylene glycol 4000 powder EMPROVE® EXPERT Ph Eur, NF
8.17007	Polyethylene glycol 6000 EMPROVE® ESSENTIAL Ph Eur, NF
8.17018	Polyethylene glycol 20000 EMPROVE® ESSENTIAL Ph Eur, NF
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
8.17045	Polyethylene glycol 3350 EMPROVE® EXPERT Ph Eur, JP, NF

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.

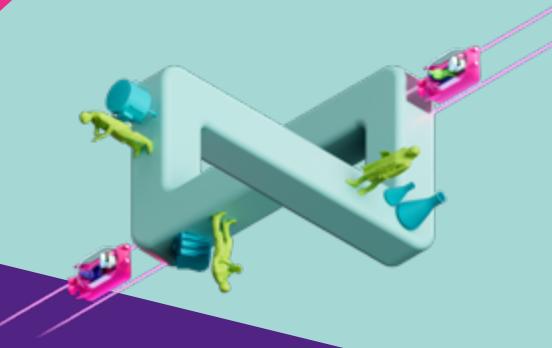
For more information, visit:

SigmaAldrich.com/formulation

Formulation Product Finder App

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Formulation-app.SigmaAldrich.com



Emprove® Program – Two Decades of Easing Risk Management

Twenty Years of Speeding up Your Journey. And Still Accelerating.

Maintaining compliance with Good Manufacturing Practices (GMP) requirements at any given time in your drug manufacturing process can be complex and challenging – especially in a global, dynamic environment. As a drug manufacturer, you need to compile a vast amount of information from your suppliers to ensure that the raw materials and components you purchase meet the technical, regulatory and supply needs for their designated application, use and function. This can be resource- and time-intensive, as well as expensive.

20 years ago, we launched the Emprove® Program to accelerate your risk assessments and help you maintain compliance. As your processes evolved, so did the Emprove® Program, anticipating challenges and keeping you ahead of the curve. With a comprehensive digital platform, the Emprove® Program speeds your drug development journey by offering convenient access to reliable information for a broad portfolio of high-quality products. This way, the Emprove® Program enables you to:

- make more agile, risk-based decisions
- maintain compliance and
- demonstrate control – saving you time and money

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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