

simplify your semi-solid formulations

High-quality pharma raw materials backed with global regulatory support

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany

SAFC®

Pharma & Biopharma Raw Material Solutions

n broad product portfolio æ 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 |

| Cat. No. | Article | |
|-------------|--|--|
| Buffers & p | 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 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 |
|---------------|--|
| 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 | |
|------------|--|--|
| Preservati | 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 |
|-------------|--|
| 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.

For more information, visit: SigmaAldrich.com/formulation

Formulation Product Finder App

Find the right product for your application with our Formulation Product Finder App at:

SigmaAldrich.com/formulationapp

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**

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice does not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For additional information, please visit SigmaAldrich.com

To place an order or receive technical assistance, please visit SigmaAldrich.com/contactAF

MilliporeSigma, the Vibrant M, Emprove, SAFC and Titriplex are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources. © 2023 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.