

**MILLIPORE
SIGMA**

quality you can count on

Addressing your requirements
for parenteral applications

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

SAFC[®]

Pharma & Biopharma Raw
Material Solutions

quality, purity, reliability.

Introducing our comprehensive product portfolio.

Sterile liquid applications demand excipients with the highest standards of quality, purity and reliability. To supply everything you need for your medicinal drug product, MilliporeSigma meets these standards at every stage of the manufacturing process. The comprehensive portfolio of high-quality pharmaceutical excipients is backed by the regulatory and quality support of the Emprove® Program and thereby helps to streamline your approval preparation and accelerate your processes. Our industry know-how, regulatory expertise and comprehensive documentation packages help you mitigate risks, and ensure a successful journey to market for your small and large volume parenteral applications.

Features:

- Emprove® Expert products with low bioburden and endotoxin limits addressing high-risk application
- Emprove® Program and documentation supporting risk assessment
- Elemental Impurity Information according to ICH Q3D

Packaging for safer pharmaceutical handling.

In addition, most of our raw materials are also available in paper free packaging such as pails, drums, pre-packs and a double PE bag, our specially-designed packaging system for clean-room manufacturing.

These stable inner and outer bags effectively prevent possible contamination from reaching sensitive production areas. After the removal of the outer bag outside of the clean room the inner bag is still labelled. This significantly minimizes risk in the handling of pharmaceutical raw materials.

Easy handling for improved process efficiency.

Caking and clumping of chemicals, dust formation and laborious weighing have a negative impact on manufacturing efficiency and may even lead to process interruptions, quality deviations and operator safety risks.

Granulated raw materials are free-flowing and easy to handle. Their greatly reduced caking behavior facilitates processability, speeds up manufacturing processes and increases operator safety.

Discover our new innovative granulated raw materials:

- Greatly reduced caking
- Better handling and processability
- Increased operator safety
- Multi-compendial
- Low endotoxin levels for high-risk applications



Discover excipients to stabilize your biomolecules.

- A portfolio of surfactants, including high-purity polysorbates with low peroxide levels
- A portfolio of stabilizers maintaining conformational protein stability including sugars, polyols and amino acids
- Multi-compendial
- Emprove® Program: low endotoxin levels for high-risk applications

Cat. No.	Article
Antioxidants	
137004	Titriplex® III (ethylene dinitrilo tetraacetic acid disodium salt dihydrate) EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP, ACS

Cat. No.	Article
Buffers & pH modifiers	
137000	Acetic acid (glacial) 100% EMPROVE® EXPERT Ph Eur, BP, JP, USP
480905	Ammonia solution 10% EMPROVE® EXPERT
103893	Benzenesulfonic acid EMPROVE® EXPERT
137002	Citric acid anhydrous powder EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS
137003	Citric acid monohydrate cryst. EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP, ACS
137044	Ethanolamine EMPROVE® EXPERT BP, NF
137007	Hydrochloric acid fuming 37% EMPROVE® EXPERT Ph Eur, BP, JP, NF, ACS
100366	(S)-Lactic acid about 90% EMPROVE® EXPERT Ph Eur, BP, E 270
137039	Potassium dihydrogen phosphate cryst. EMPROVE® EXPERT Ph Eur, BP, JPC, NF
137010	di-Potassium hydrogen phosphate anhydrous EMPROVE® EXPERT Ph Eur, BP, USP
480864	Potassium hydroxide solution 46–48% EMPROVE® EXPERT
137046	Sodium acetate anhydrous EMPROVE® EXPERT USP
128205	Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
137014	Sodium carbonate anhydrous EMPROVE® EXPERT Ph Eur, BP, JP, NF
137042	tri-Sodium citrate dihydrate cryst. EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS
137018	Sodium dihydrogen phosphate dihydrate EMPROVE® EXPERT Ph Eur, BP, USP, JPE
137093	Sodium dihydrogen phosphate monohydrate EMPROVE® EXPERT BP, USP
137036	di-Sodium hydrogen phosphate dihydrate EMPROVE® EXPERT Ph Eur, BP, USP
137092	di-Sodium hydrogen phosphate heptahydrate EMPROVE® EXPERT DAC, USP
137013	Sodium hydrogen carbonate EMPROVE® EXPERT Ph Eur, BP, USP, JP
137020	Sodium hydroxide pellets EMPROVE® EXPERT Ph Eur, BP, JP, NF, ACS
106522	Sodium-(S)-lactate-solution about 50% EMPROVE® EXPERT Ph Eur, BP, USP
137148	Triethanolamine (Trolamine) EMPROVE® EXPERT Ph Eur, NF
108307	Tris(hydroxymethyl)aminomethane (Trometamol) high purity EMPROVE® EXPERT Ph Eur, BP, ChP, JPC, USP, ACS

Cat. No.	Article
Mineral salts	
101816*	Ammonium sulfate EMPROVE® EXPERT ACS, NF
128218	Ammonium sulfate EMPROVE® EXPERT ChP, NF, ACS
137101	Calcium chloride dihydrate EMPROVE® EXPERT Ph Eur, BP, JP, USP
137008	Magnesium chloride hexahydrate cryst. EMPROVE® EXPERT Ph Eur, BP, USP, JPC, ACS
104165	Potassium chloride granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP
137009	Potassium chloride EMPROVE® EXPERT Ph Eur, BP, USP, JP
137017	Sodium chloride EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
137144	Sodium sulfate anhydrous EMPROVE® EXPERT Ph Eur, USP, BP

*for U.S. & Canada only

Click. Explore. Learn more.

Biopharmaceutical Application Guide

Identify the relevant products for your process:

[EMDMillipore.com/BAG](https://www.emdmillipore.com/BAG)

Pharmaceutical Application Guide

A search tool to help you overcome your process challenges:

[EMDMillipore.com/PAG](https://www.emdmillipore.com/PAG)

Risk Mitigation Tool

Get guidance through the challenges and quality requirements of your bio-manufacturing process:

[EMDMillipore.com/emprove-risk-mitigation](https://www.emdmillipore.com/emprove-risk-mitigation)

Formulation Product Finder App

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

[EMDMillipore.com/formulationapp](https://www.emdmillipore.com/formulationapp)

Cat. No.	Article
Preservatives	
137123	Benzalkonium chloride EMPROVE® EXPERT Ph Eur, NF
137124	Benzalkonium chloride (50% aqueous solution) EMPROVE® EXPERT Ph Eur, NF
137120	Benzyl alcohol EMPROVE® EXPERT Ph Eur, ChP, JP, NF
100987	Benzyl alcohol special grade (benzaldehyde ≤ 0.05%) EMPROVE® EXPERT Ph Eur, BP, JP, NF

Cat. No.	Article
Solvents	
137117	Dimethyl Sulfoxide EMPROVE® EXPERT Ph Eur, USP
100971	Ethanol 96% EMPROVE® EXPERT Ph Eur, BP, ChP
100967	Ethanol 96% EMPROVE® EXPERT Ph Eur, ChP, JP, USP
100986	Ethanol absolute EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
137028	Glycerol anhydrous (vegetable) EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS
107478	1,2-Propanediol EMPROVE® EXPERT Ph Eur, BP, USP

Cat. No.	Article
Stabilizers – Amino acids	
112488	N-Acetyl-DL-tryptophan EMPROVE® EXPERT Ph Eur, BP
101700	L-Alanine EMPROVE® EXPERT Ph Eur, USP
101587	L-Arginine EMPROVE® EXPERT Ph Eur, ChP, JP, USP
101544	L-Arginine monohydrochloride EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
100590	Glycine cryst. EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
103669	Glycine granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
104352	L-Histidine EMPROVE® EXPERT Ph Eur, ChP, JP, USP
104354	L-Histidine monohydrochloride monohydrate EMPROVE® EXPERT Ph Eur, BP, ChP, JP
105020	L-Leucine EMPROVE® EXPERT Ph Eur, USP
107267	L-Phenylalanine EMPROVE® EXPERT Ph Eur, USP
107430	L-Proline EMPROVE® EXPERT Ph Eur, USP
107647	L-Serine EMPROVE® EXPERT Ph Eur, USP
108396	L-Tryptophan EMPROVE® EXPERT Ph Eur, BP, JP, USP
108378	L-Tyrosine EMPROVE® EXPERT Ph Eur, JP, USP

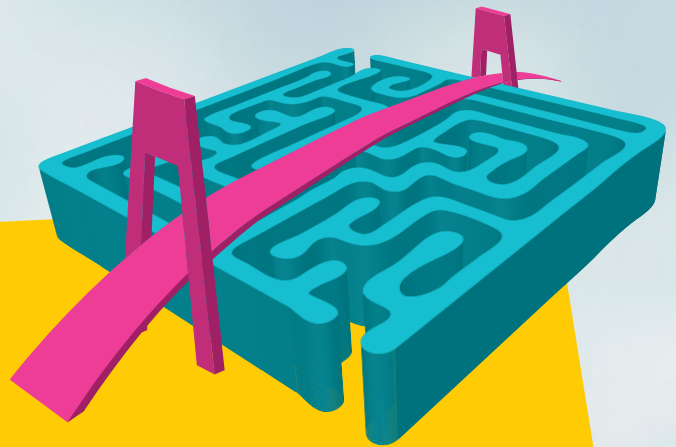
Cat. No.	Article
Stabilizers – Sugars & sugar derivatives	
142020	Cyclodextrin HPB EMPROVE® EXPERT Ph Eur, NF
137048	D(+)-Glucose anhydrous EMPROVE® EXPERT Ph Eur, BP, USP, ACS
108346	D(+)-Glucose monohydrate EMPROVE® EXPERT Ph Eur, BP, USP
137028	Glycerol anhydrous (vegetable) EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS
137045	Lactose monohydrate powder EMPROVE® EXPERT Ph Eur, BP, NF, JP
137096	D(-)-Mannitol EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
111597	Parteck® SI 400 LEX (Sorbitol) suitable for use as excipient EMPROVE® exp Ph Eur, BP, NF, JP
103789	Sucrose EMPROVE® EXPERT Ph Eur, ChP, JP, NF
102776	Trehalose dihydrate EMPROVE® EXPERT Ph Eur, ChP, NF, JP

Cat. No.	Article
Stabilizers – Others	
100002	Tri-n-butyl phosphate EMPROVE® EXPERT Ph Eur
817081	Sodium caprylate EMPROVE® EXPERT Ph Eur, ChP, NF
137004	Titriplex® III (Ethylene dinitrilo tetraacetic acid disodium salt dihydrate) EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP
137030	Urea cryst. EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS
104166	Urea granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS

Cat. No.	Article
Surfactants	
137112	Poloxamer 188 EMPROVE® EXPERT (stabilized with 70ppm BHT) Ph Eur, NF
137172	Polysorbate 20 high purity EMPROVE® EXPERT Ph Eur, ChP, JPE, NF
137171	Polysorbate 80 high purity EMPROVE® EXPERT Ph Eur, ChP, JPE, NF

SAFC®

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Material Solutions



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 helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To help you optimize your process, our Emprove® Program provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. The Emprove® Program 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: EMDMillipore.com

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