

**MILLIPORE  
SIGMA**

# keep a close eye on quality and safety

With our excipients for  
ophthalmic drug formulation

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

**SAFC**<sup>®</sup>

Pharma & Biopharma Raw  
Material Solutions

# Reduce risk and overcome challenges

Ophthalmic drugs pose special formulation challenges to manufacturers. In general, choosing the right processes and materials is important to ensure the required quality, drug tolerability and patient adherence. Formulators must pay attention to tonicity, pH, stability and viscosity, as well as sterility and microbiological purity, which has to be assured throughout the time of use. The final ophthalmic formulation must remain sterile, microbially pure, and stable throughout shelf life. Finding the right excipient that supports these needs is key.

Our large product portfolio covers all excipient groups required for ophthalmic formulation, such as viscosity enhancers, surfactants, buffers and pH regulation agents, isotonicity adjusting agents as well as antioxidants and preservatives – all in the right quality.

## Mitigate risk during formulation development.

For an ophthalmic formulation to succeed, making sure all of its properties are in line with regulatory guidelines right from the start is essential.

We are aware that developing formulations to treat ocular diseases is challenging and that requirements for the final product are high. To support full supply chain transparency and risk mitigation, we not only provide excipients in the highest quality but also in-depth, consistent documentation in a centralized location, so you can access the information you need when you need it. And when it comes to regulatory expertise, our experts are always here to support you.

**Our Emprove® Program, along with the Emprove® Expert portfolio range, combines comprehensive documentation with excellent service, to support risk assessment and qualification for your ophthalmic process.**

## Features

- A vast portfolio of top-quality raw materials for all dosage forms in line with ophthalmic industry standards and needs
- Seamless service to support your process from formulation to final fill
- Special capabilities and services such as customized packaging available on request
- Comprehensive ready-to-use Emprove® documentation

## Benefit from PVA that meets your needs.

Our portfolio offers a wide range of polyvinyl alcohol (PVA) grades of different viscosities, molecular weights, and degrees of hydrolysis. This way, we can provide you with a high-quality product for your exact need and application.

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

## Make the most of our preservatives.

Preservatives are used in liquid and semi-solid formulations to prevent microbial growth in pharmaceutical products and to increase the products' shelf life. The solubility and chemical properties of preservatives mean they can be used in different types of formulations.

We offer a broad portfolio of preservatives suitable for multiple administration routes and dosage forms. And to help you navigate regulatory challenges, manage risks, and improve your manufacturing processes, we offer comprehensive documentation as part of our Emprove® Program.

- Comprehensive portfolio of products
- Multi-compendial
- Emprove® Program and documentation

## Explore our Trehalose for high-risk applications.

The disaccharide trehalose is widely used in a variety of pharmaceutical formulations as a bioprotectant, osmoprotectant and stabilizer. In ophthalmics, it is employed in the treatment of dry eye syndrome.

Our product Trehalose dihydrate Emprove® Expert is low in endotoxins and bioburden, making it the right choice for your high-risk applications.

- Multi-compendial, including ChP
- China registration dossier submitted
- Low endotoxin limit ( $\leq 0.3$  I.U./g)
- High-quality grade in a market with limited number of suppliers
- Emprove® Program and documentation

## Rely on our high-quality APIs.

Our active pharmaceutical ingredients (APIs) are suitable for ophthalmic formulations for eye diseases (e.g. for inflammation, cataract and dry eye syndrome) and can be used as alternatives to antibiotics. Backed by industry-leading production know-how and comprehensive regulatory support, our range of high-quality APIs provides you with all the information and support you need for your ophthalmic product.

- High-quality products
- Manufactured under cGMP ICH Q7 guideline
- CEP and US-DMF available
- Dedicated regulatory support worldwide throughout the entire registration process and an excellent compliance track record
- Emprove® API Information Package available for your risk assessment and qualification

# 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:  
[EMDMillipore.com/emprove](https://EMDMillipore.com/emprove)

Cat. No.	Article
<b>Buffers &amp; pH Modifiers</b>	
100160	Boric acid cryst. EMPROVE® ESSENTIAL Ph Eur,BP,NF
100162	Boric acid powder EMPROVE® ESSENTIAL Ph Eur,BP,NF
100247	Citric acid anhydrous fine-granular EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC
100241	Citric acid anhydrous powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC
100242	Citric acid monohydrate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC
100243	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC
100844	Ethanolamine EMPROVE® ESSENTIAL BP,NF
100314	Hydrochloric acid fuming 37% EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF
100563	ortho-Phosphoric acid 85% EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF,E 338
104820	Potassium acetate, extra pure Ph Eur, BP, E 261
104871	Potassium dihydrogen phosphate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,JPC,NF,E 340
104956	tri-Potassium citrate monohydrate EMPROVE® ESSENTIAL Ph Eur,BP,USP,FCC,E 332
105101	di-Potassium hydrogen phosphate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,E 340
106281	Sodium acetate anhydrous EMPROVE® ESSENTIAL USP,FCC,E 262
106265	Sodium acetate trihydrate extra pure EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,FCC,E 262
111037	tri-Sodium citrate anhydrous EMPROVE® ESSENTIAL USP,FCC,E 331
106432	tri-Sodium citrate dihydrate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 331
106446	tri-Sodium citrate dihydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 331
137042	tri-Sodium citrate dihydrate cryst. EMPROVE® EXPERT Ph Eur,BP,JP,USP,ACS
106447	tri-Sodium citrate dihydrate EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 331
106345	Sodium dihydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur,BP,USP,JPE,E 339
106431	tri-Sodium citrate 5,5-hydrate EMPROVE® ESSENTIAL FU VIII,E 331
106349	Sodium dihydrogen phosphate monohydrate EMPROVE® ESSENTIAL BP,USP
106585	di-Sodium hydrogen phosphate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,USP,JPE,E 339

106576	di-Sodium hydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur,BP,USP
106573	di-Sodium hydrogen phosphate dodecahydrate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP
106574	di-Sodium hydrogen phosphate heptahydrate EMPROVE® ESSENTIAL DAC,USP
106482	Sodium hydroxide pellets EMPROVE® ESSENTIAL Ph Eur,BP,FCC,JP,NF,E 524
106303	di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF
100713	Sulfuric acid 95-98 % EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF
108386	Tris(hydroxymethyl)aminomethane (Trometamol) EMPROVE® ESSENTIAL Ph Eur,BP,JPC,USP

Cat. No.	Article
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### Tonicity Agents

137101	Calcium chloride dihydrate EMPROVE® EXPERT Ph Eur,BP,JP,USP
104091	Glycerol 85% EMPROVE® EXPERT Ph Eur,BP
137028	Glycerol anhydrous (vegetable) EMPROVE® EXPERT Ph Eur,BP,JP,USP,ACS
137008	Magnesium chloride hexahydrate cryst. EMPROVE® EXPERT Ph Eur,BP,USP,JPC,ACS
137096	D(-)-Mannitol EMPROVE® EXPERT Ph Eur,BP,USP,JP
111597	Parteck® SI 400 LEX (Sorbitol) EMPROVE® exp Ph Eur, BP, NF, JP
137009	Potassium chloride EMPROVE® EXPERT Ph Eur,BP,USP,JP
137017	Sodium chloride EMPROVE® EXPERT Ph Eur,BP,JP,USP
102776	Trehalose dihydrate EMPROVE® EXPERT Ph Eur,ChP,NF,JP

Cat. No.	Article
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### Antioxidants & Preservatives

137124	Benzalkonium chloride (50% aqueous solution) EMPROVE® EXPERT Ph Eur,NF
137123	Benzalkonium chloride EMPROVE® EXPERT Ph Eur,NF
100160	Boric acid cryst. EMPROVE® ESSENTIAL Ph Eur,BP,NF
100162	Boric acid powder EMPROVE® ESSENTIAL Ph Eur,BP,NF
106756	Methyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur,BP,NF
106757	Methyl 4-hydroxybenzoate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,FCC
105119	Potassium sorbate granules EMPROVE® ESSENTIAL Ph Eur,BP,NF,FCC,E 202
105118	Potassium sorbate powder EMPROVE® ESSENTIAL Ph Eur,BP,NF,FCC,E 202
107427	Propyl 4-hydroxybenzoate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,FCC
107428	Propyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph Eur,BP,NF
106357	Sodium disulfite (sodium metabisulfite) EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,E 223
106514	Sodium thiosulfate pentahydrate cryst. EMPROVE® ESSENTIAL Ph Eur,BP,USP
100662	Sorbic acid EMPROVE® ESSENTIAL Ph Eur,BP,NF,FCC,E 200
817043	Thimerosal EMPROVE® ESSENTIAL Ph Eur,BP
137004	Titriplex® III (ethylene dinitrilo tetraacetic acid disodium salt dihydrate) EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP,ACS
101005	1,1,1-Trichloro-2-methyl-2-propanol hemihydrate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF

Cat. No.	Article
<b>Viscosity Enhancers</b>	
817001	Polyethylene glycol 200 EMPROVE® ESSENTIAL DAB 8
817002	Polyethylene glycol 300 EMPROVE® ESSENTIAL Ph Eur
817003	Polyethylene glycol 400 EMPROVE® ESSENTIAL Ph Eur,JP
817004	Polyethylene glycol 600 EMPROVE® ESSENTIAL Ph Eur
141350	Polyvinyl alcohol 4-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
141354	Polyvinyl alcohol 5-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
141351	Polyvinyl alcohol 8-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
141355	Polyvinyl alcohol 18-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
141352	Polyvinyl alcohol 26-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
141353	Polyvinyl alcohol 40-88 EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
141356	Polyvinyl alcohol 28-99 EMPROVE® ESSENTIAL Ph Eur,JPE

Cat. No.	Article
<b>Solvents</b>	
100967	Ethanol 96% EMPROVE® EXPERT Ph Eur,JP,USP
100986	Ethanol absolute EMPROVE® EXPERT Ph Eur,BP,JP,USP
104091	Glycerol 85% EMPROVE® EXPERT Ph Eur,BP
137028	Glycerol anhydrous (vegetable) EMPROVE® EXPERT Ph Eur,BP,JP,USP,ACS
107478	1,2-Propanediol EMPROVE® ESSENTIAL Ph Eur,BP,USP

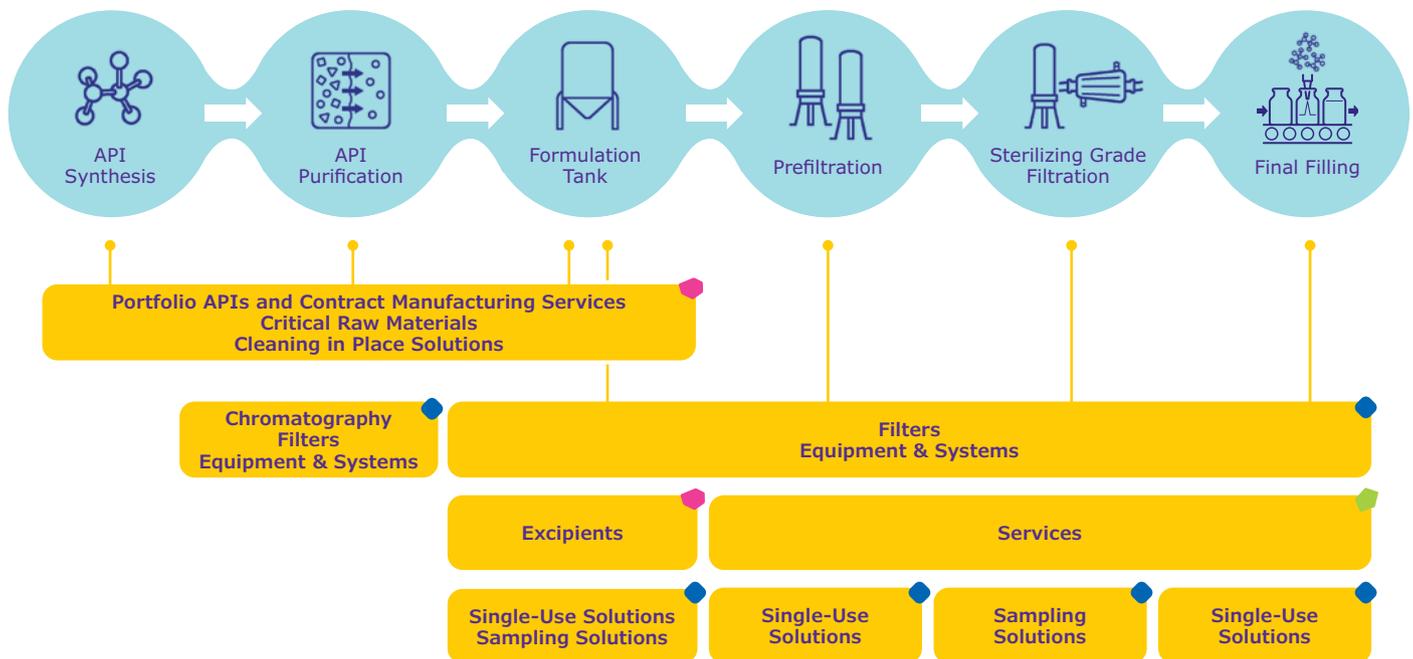
Cat. No.	Article
<b>Surfactants &amp; Solubility Enhancing Agents</b>	
142020	Cyclodextrin HPB EMPROVE® EXPERT Ph.Eur.,NF
137112	Poloxamer 188 EMPROVE® EXPERT (stabilized with 70ppm BHT) Ph Eur,NF
817072	Tween® 20 (Polysorbate) EMPROVE® ESSENTIAL Ph Eur,JPE,NF
817061	Tween® 80 (Polysorbate) EMPROVE® ESSENTIAL Ph Eur,JP,NF

Cat. No.	Article
<b>Active Pharmaceutical Ingredients</b>	
586409	Arcofolin™ L-Methylfolate
819110	Bibrocathol
100164	Boric acid EMPROVE® API Ph Eur,BP,NF
102465	Calcium chloride dihydrate EMPROVE® API Ph Eur,BP,JP,USP
102367	Magnesium chloride hexahydrate EMPROVE® API Ph Eur,BP,JPC,USP
106444	Sodium chloride EMPROVE® API Ph Eur,BP,JP,USP

# Ophthalmics Process

When designing a manufacturing process for ophthalmic products and selecting a supplier, it is important to consider the full breadth of needs from API synthesis to final filling:

- An integrated portfolio and contract manufacturing capabilities in APIs, critical raw materials (Chemiflex™), intermediates, solvents, excipients and other reagents (incl. cleaning in place) to ensure the required performance, quality and regulatory compliance in every step of your process
- Services to support development, compatibility and integrity testing
- A comprehensive range of chromatography solutions, filters and hardware for your purification steps
- Final filters to ensure bioburden and particulate control and sterility in aseptic processes
- Regulatory expertise and comprehensive documentation to meet stringent regulatory requirements



## Choose a supplier who possesses the right solutions for your particular process:

We provide regulatory know-how, an integrated portfolio and applications expertise for all steps in the ophthalmic process. Our Emprove® Program combines outstanding quality with comprehensive documentation and excellent service, to support risk assessment and qualification.

**SAFC®**  
Pharma & Biopharma Raw  
Material Solutions

**BioReliance®**  
Pharma & Biopharma  
Manufacturing &  
Testing Services

**Millipore®**  
Preparation, Separation,  
Filtration & Testing Products

# Pharmaceutical Application Guide

## More than just excipients!

We provide a comprehensive portfolio of everything you need for your ophthalmics process. Whether you need cleaning in place solutions, filters for effective particle retention and sterility assurance, or single-use solutions and sampling systems to minimize risk of contamination – we are the right partner. Explore products and services for each step of your pharmaceutical manufacturing process:

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



## Click. Explore. Learn more.

### Formulation Product Finder App

Find the right product for your application with our Formulation Product Finder App at: [EMDMillipore.com/formulationapp](https://www.emdillipore.com/formulationapp)

### Risk Mitigation Tool

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

[EMDMillipore.com/improve-risk-mitigation](https://www.emdillipore.com/improve-risk-mitigation)

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](https://www.emdillipore.com)

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To place an order or receive technical assistance, please visit [EMDMillipore.com/contactPS](https://www.emdillipore.com/contactPS)

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