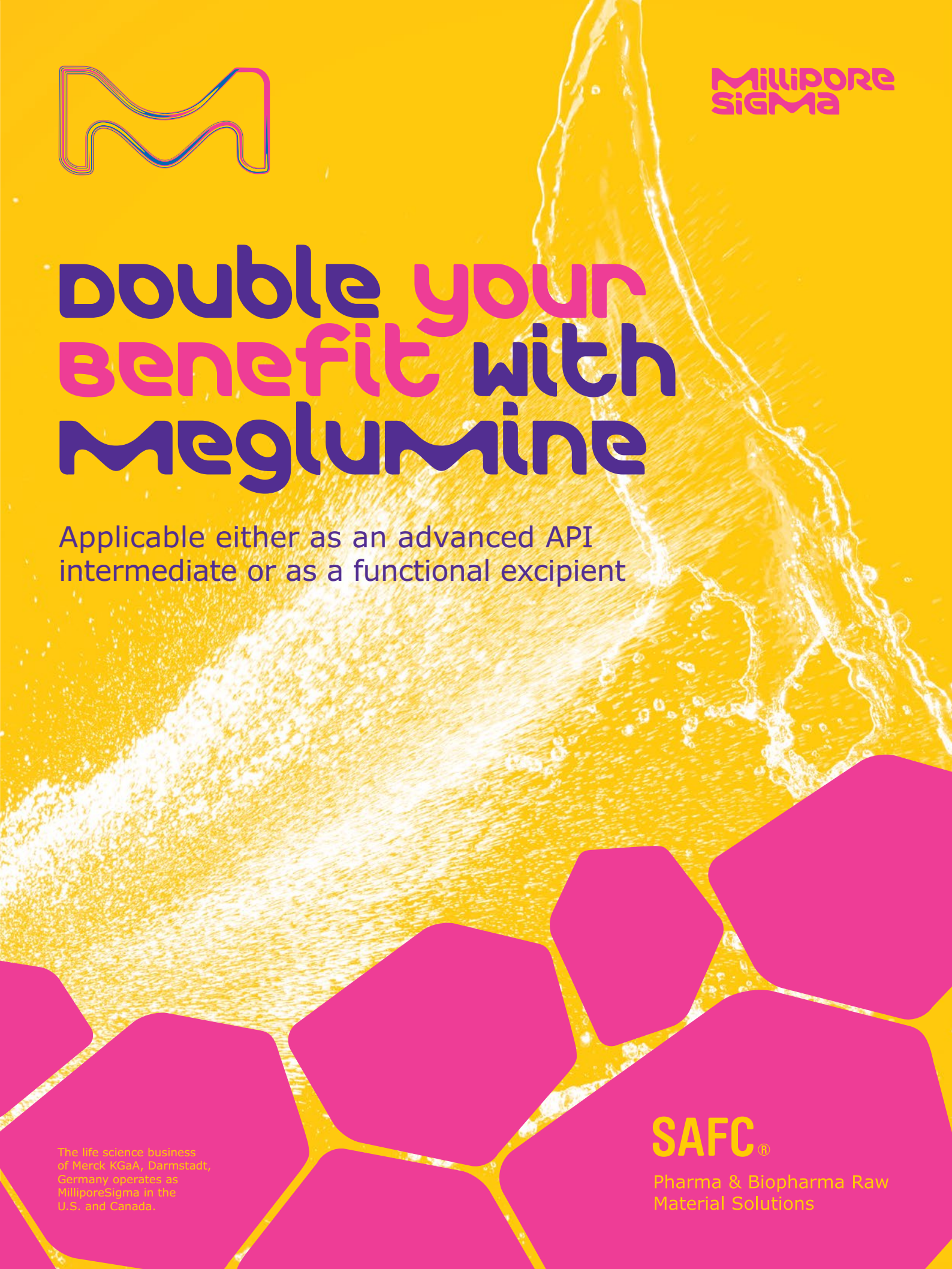

Double your benefit with Meglumine

Applicable either as an advanced API intermediate or as a functional excipient

SAFC®

Pharma & Biopharma Raw Material Solutions

we've got you covered

Solubility and bioavailability of the API are key challenges for a formulator. To ensure a formulation's success and bring it to the market without delay, using the right grade and quality of materials is critical.

Meglumine is a versatile product applied either as a counterion to form a salt with the API or as a functional excipient. Traditionally applied as counterion in contrast media, meglumine can be also used to enhance API solubility, improve API stability, and adjust pH value. Applications include solid and liquid formulations, such as tablets, injectables, ophthalmics as well as topical dosage forms. Depending on your application, meglumine needs to meet different requirements.

Our state-of-the-art production site in Mollet del Vallès, Spain manufactures API-grade meglumine according to the latest regulatory guidelines, as advocated by the FDA and EMA. Furthermore, our meglumine is also available as an Emprove® Essential excipient.

We offer industry-leading support during the entire registration process and boast an excellent track record facilitating compliance with international standards. In addition, the quality, consistency and compliance of our raw materials is fully documented and supported by a secure and robust supply chain.

Benefits

- Solubility and bioavailability enhancement of active pharmaceutical ingredients (API).
- Excellent counterion performance, a viable alternative to sodium.
- API grade manufactured under the cGMP ICH Q7 guideline for APIs.
- Sole manufacturing location for API-grade meglumine in Europe.
- Multi-compendial product, complying with all major pharmacopeias, including ChP.
- Meglumine EMPROVE® API has also been successfully co-reviewed in China.

Product Profile

Product name	Meglumine low in endotoxins EMPROVE® API Ph Eur, JP, ChP, USP Meglumine EMPROVE® ESSENTIAL Ph Eur, ChP, JP, USP
Production process	Multiple synthesis steps in dedicated equipment
Regulatory status	GMP, certified by Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for API grade; validated process (according to ICH Q7)
Track record	FDA audits; AEMPS audits
Registrations	US-DMF, CEP, Chinese Co-review
Production site	Mollet del Vallès, Spain

Application range of Meglumine

Advanced intermediate API
Meglumine-API salt with meglumine as counterion
pK_a of Meglumine: 9.60 Suitable for APIs with a pK_a of 6 or lower
→ Meglumine is therefore part of the API
API-grade material is expected

Functional excipient
pH modifier
Solubilizer
Alkalizer
Stabilizer
→ A complex with the active formed in the body
API or excipient grade acceptable

API quality for advanced intermediates

According to the FDA, different salt forms of a drug substance are considered different APIs.

- → Consequently, the counterion is considered part of the API.
- → Therefore, both the API and the meglumine counterion should be manufactured according to ICH Q7.

For excipient applications, the same API-grade quality can be assured, with the additional excipient requirements provided in the Emprove® dossier, making Meglumine EMPROVE® ESSENTIAL an ideal product for excipient applications.

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

Ordering Information

Cat. No.	Product	Pack Size	Packaging
1.06143.1000	Meglumine low in endotoxins EMPROVE® API Ph Eur, ChP, JP, USP	1 kg	Plastic bottle in corrugated box
1.06143.9025		25 kg	PE bag in PE square drum*
1.06143.9026		25 kg	PE bag in PE square drum*
1.06143.9030		25 kg	PE bag in plastic drum
1.06143.9050		50 kg	PE bag in plastic drum
1.06187.1000	Meglumine EMPROVE® ESSENTIAL Ph Eur, ChP, JP, USP	1 kg	Plastic bottle in corrugated box
1.06187.9029		25 kg	PE bag in PE square drum

*CP3 pallets are used for article .9025, EURO pallets are used for article .9026

Formulation Product Finder App

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

EMDMillipore.com/formulationapp

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**

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 **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contacts**

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