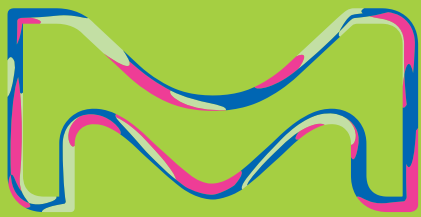


**SAFC®**

Pharma/Biopharma Raw Materials

## API-grade Meglumine



### **A functional excipient & counterion that fulfills all of your needs**

Opened in September 2016, our new state-of-the-art production site in Mollet, Spain manufactures API-grade Meglumine according to the latest regulatory guidelines, as advocated by the FDA and EMA.

We offer best-practice support throughout your entire registration process and boast an excellent track record facilitating our customers' compliance with international standards.

#### **Benefits of our Meglumine:**

- Enhances the solubility and bioavailability of actives
- An excellent substitute for sodium
- Manufactured under cGMP guideline ICH Q7\* for active pharmaceutical ingredients (API)
- Only location in Europe where Meglumine is manufactured

\*International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

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

**MERCK**

## PRODUCT PROFILE

<b>Product description</b>	Meglumine is low in endotoxins suitable for use as Active Pharmaceutical Ingredient Emprove® API Ph Eur, JP, USP
<b>Pack sizes</b>	25 kg and 50 kg carton box and/or PE drums with double PE bags
<b>Production process</b>	Multiple synthesis steps in dedicated equipment
<b>Regulatory status</b>	GMP, validated process (according to ICH Q7)
<b>Track record</b>	Customer audits: no critical findings FDA audits: no major observations
<b>Registrations</b>	US-DMF*, CEP*
<b>Production site</b>	Mollet, Spain

\*Registration is being processed to add Mollet as an additional manufacturing site

## APPLICATION RANGE OF MEGGLUMINE

### As an advanced intermediate API

- Salt of Meglumine and the active is applied
- Meglumine has to be considered as part of the API
- pKa of Meglumine: 9.60
- Suitable for APIs with a pKa of 6 or lower

API-grade material is mandatory

### As a functional excipient

- pH modifier
- Alkalizer
- Stabilizer
- A complex with the active formed in the body
- Meglumine has to be considered as part of the API

API-grade material is strongly recommended

## WHY API QUALITY?

### Consequence from FDA and EMA statements:

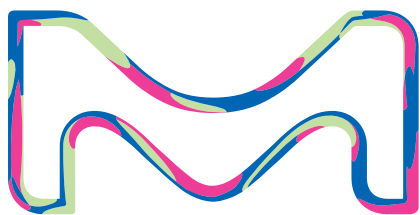
According to the FDA, different salt forms of a drug substance MUST be considered as different APIs.

Consequently, the counterion MUST be considered as part of the API.

The manufacture of an API is performed according to ICH Q7.

**The manufacture of the counterion has to be performed according to ICH Q7**

**The same is recommended for the application as a functional excipient, as a complex with the active formed in the body**



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, from the website: [www.merckmillipore.com](http://www.merckmillipore.com)

### Merck KGaA, Darmstadt, Germany

Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt  
Germany  
Phone: +49 6151 72-0  
Email: [pcs.sale-supportEU@merckgroup.com](mailto:pcs.sale-supportEU@merckgroup.com)

[www.merckmillipore.com](http://www.merckmillipore.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 do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.