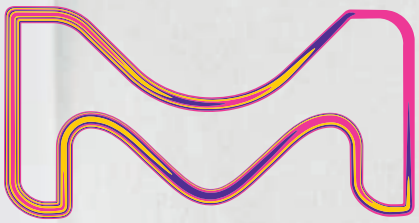
MilliporeSigma

The ideal fit for your API synthesis

The Chemiflex Critical Raw Materials Program.



SAFC®

Pharma & Biopharma Raw Material Solutions

CRITICAL RAW MATERIALS – QUALITY & DOCUMENTATION MATCHING YOUR NEEDS

Getting it right is our ultimate goal. Which means providing flexible, to-the-point offerings for your API synthesis along your molecule journey – with the right documentation and product quality to match your needs.

MilliporeSigma Chemiflex, our new comprehensive program, enables you to customize all relevant properties of your API synthesis including material, quality, quantity and in consequence: risk mitigation.

It's an integrated approach to the synthesis of APIs that includes extensive documentation, helping you bridge every regulatory gap between non-clinical and commercial phases, offering global support through our local ressources in Europe, Asia and North America.

In other words: flexibility is paramount. Because we know from experience that designing processes means relying on products – and a partner – to adapt to your individual requirements, and not the other way round.

Unique support for individual needs

Custom manufactured

API Starting Materials

Qualification (supplier, supply chain) documentation, e.g.:

- Change control
- Supplier qualification/ Supply chain
- Residual solvents/EI
- BSE/TSE

Intermediates

- ICH Q7 GMP
- Documentation on API level

Emprove® portfolio

Solvents and Reagents

Qualification (supplier, supply chain) documentation, e.g.:

- Change control
- Supplier qualification/ Supply chain
- Residual solvents/EI
- BSE/TSE

MilliporeSigma Chemiflex: A comprehensive program with benefits that add up

- Accelerate your time to market by covering all facets of your API synthesis from a single supplier.
- Find peace of mind thanks to our unique combination of product portfolio and customized services including appropriate documentation as well as regulatory support.
- Mitigate your risks through industry-leading expertise, regulatory thought leadership and platform approach.
- Enjoy next-level flexibility with our broad portfolio (partly within Emprove® documentation).
- Benefit from a high degree of customization that covers a wide range of products.
- Get the right support throughout all stages of your API synthesis, from early non-clinical through commercial launch and beyond.
- In short: Let us make your future molecule possible.

Our selected portfolio of critical raw materials

Product no.	Product
100013	**Acetone,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, JPE, NF
106049	**Dichloromethane,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, NF
100967	**Ethanol abs./96%,** suitable for use as excipient EMPROVE® exp Ph Eur, JP, USP
100995	**2-Propanol,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP
106008	**Methanol** suitable for use as excipient EMPROVE® exp Ph Eur, BP, JPE, NF
137117	**DMSO,** suitable for use as excipient EMPROVE® exp Ph Eur, USP

Product no.	Product
104091	**Glycerol anhyd./85%,** suitable for use as excipient EMPROVE® exp Ph Eur, BP
103000	**Triacetin,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP
100864	**Ethyl acetate,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, NF
100926	**Diethyl ether,** suitable for use as excipient EMPROVE® exp Ph Eur, BP
100988	**1-Butanol,** suitable for use as excipient EMPROVE® exp NF
107478	**1,2-Propanediol,** suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP

New introduction, available as of Q1 2019:
Acetronile + Tetrahydrofuran.

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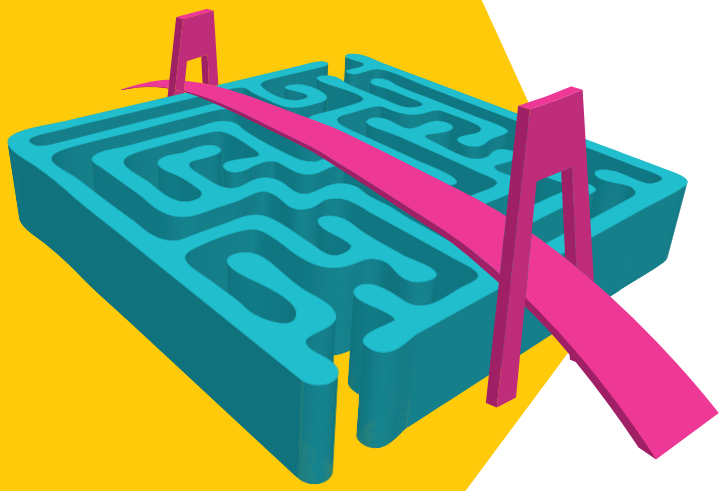
For more information visit:
sigmaaldrich.com/chemiflex



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. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented by three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at: **EMDMillipore.com/emprove**

Emprove® Suite provides 24/7 access to all Emprove® dossiers online. For more information on how to subscribe, please visit: **EMDMillipore.com/emprovesuite**

The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: **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 do 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/contactPS**

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