

SAFC®

Pharma & Biopharma Raw
Material Solutions

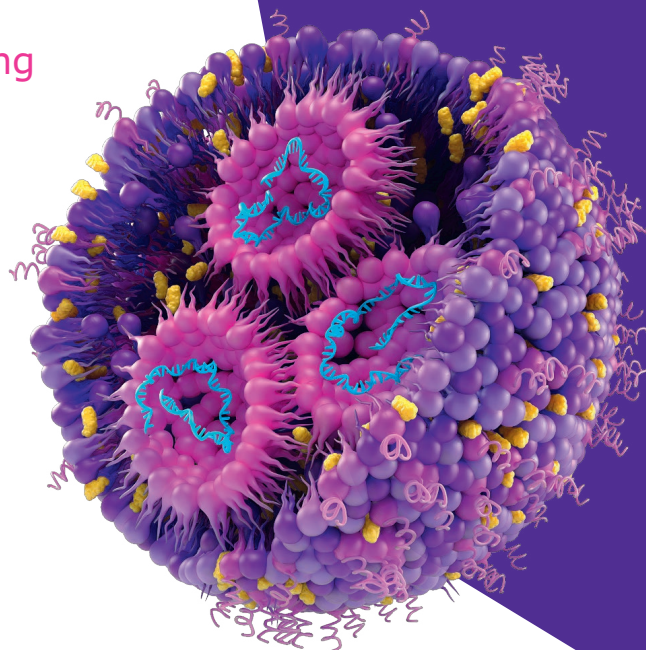
MERCK

Lipids for pharmaceutical applications

Your global partner for the manufacturing
of synthetic lipids.

A GMP-scalable process which yields a high-quality lipid is essential to lipidic drug product development and manufacturing. We are highly specialized in synthesizing top-quality GMP lipids for pharmaceutical applications and gene therapy, focusing on tailored manufacturing to meet your specific needs. We also offer an off-the-shelf catalog with optimized stability, solubility, and handling characteristics. If lipid blends are needed, we can provide lyophilization and spray drying.

Our sites all over the world, including Western Europe, meet the high regulatory demands for the manufacture of synthetic lipids, using ICH Q7-compliant quality systems. Committed to consistently high product quality, reliability of supply, and short delivery timelines, we assist you through all phases of clinical development and commercialization and help you meet your development milestones.



Our offering:

- Support in every phase of development and marketing
- cGMPs and site standards that follow the concepts of ICH Q7
- Consistently high product quality from grams to tons
- Strong expertise in lipids analytics, including analytical method development, and stability studies
- Regulatory support and technical expertise
- An excellent track record of customer and FDA audits
- Custom manufacturing support including new chemical synthesis route finding
- Bovine Spongiform Encephalopathy (BSE) & Transmissible Spongiform Encephalopathies (TSEs) free certificates

Our portfolio of lipids:

| Neutral lipids | Cationic lipids | PEG lipids | Phospholipids | Others |
|--|--|---|--|---|
| Synthetic cholesterol³⁾ Cat. No. W004591 Cat. No. 104672 | (R,S)-DOTAP CI¹⁾ Cat. No. CH2900014 (R) | mPEG 2k DSG Cat. No. 5724952900 | DOPC¹⁾ Cat. No. CH2900013 | Squalene Cat. No. ARK2140 |
| Isomeric Mix 1,2/1,3-GDO Cat. No. 5880852900 | (R)-DOTAP CI^{1,2)} Cat. No. CH2900029 | mPEG 2k DMG Cat. No. 5786322900 | DPPC Cat. No. CH2900047 | Palmitic acid Cat. No. W50230 |
| Tripalmitin¹⁾ Cat. No. W50222 | (S)-DOTAP CI²⁾ Cat. No. CH2900030 | ALC-0159²⁾ Cat. No. 586054 | DOPE Cat. No. 5002602900 | CHEMS Cat. No. CH2900012 |
| | (R)-DODMA Cat. No. 5002442900 | | DSPC Cat. No. W2660 | |
| | (R)-DOTMA CI Cat. No. 5002492900 | | | |
| | ALC-0315²⁾ Cat. No. 585807 | | | |

¹⁾ Type II US-DMF is filed with the US FDA.

²⁾ Indication or license restriction.

³⁾ Dual sourcing capabilities.

We have over 25 years of experience in custom manufacturing and specialize in the synthesis of

- Ionizable lipids
- PEGylated lipids
- Targeted lipids

Don't find what you're looking for?

Please contact us to find out more about the alternative lipid solutions we provide through custom manufacturing and our collaboration partners: www.MerckMillipore.com/contactPS

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 www.MerckMillipore.com

To place an order or receive technical assistance, please visit www.MerckMillipore.com/contactPS

