

Lipids for pharmaceutical applications

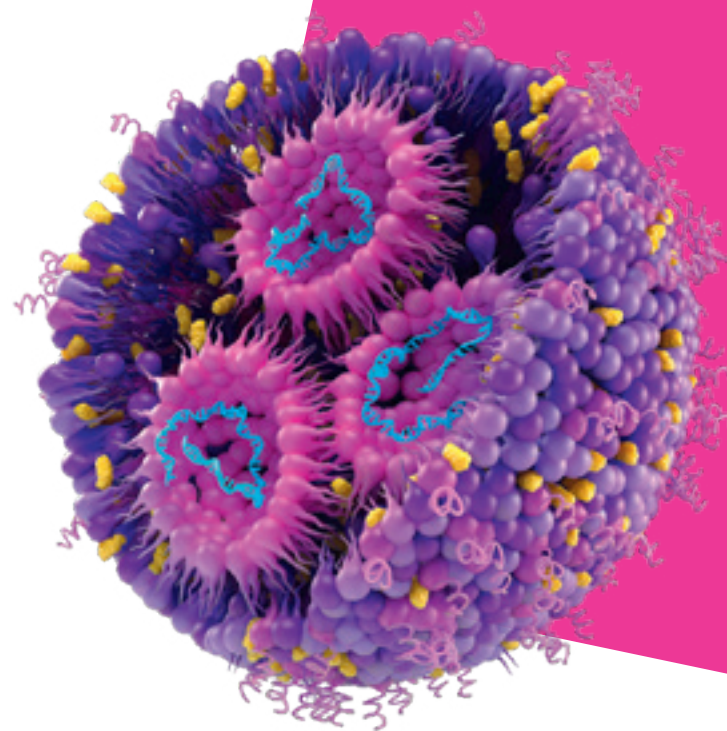
Your global partner for the manufacturing of synthetic lipids.

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 lipids with optimized stability, solubility, and handling characteristics.

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

Our Millipore® CTDMO Services support your custom lipid synthesis needs at every phase of development, from non-GMP samples all the way to commercially-validated GMP material.

Our SAFC® portfolio of lipids allows you to purchase off-the-shelf, high quality lipids to readily test and use in your formulations.



Lipids Excellence

- 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
- An excellent track record of customer and FDA audits
- Strong expertise in lipids analytics, including analytical method development, and stability-studies
- Phase-appropriate regulatory support and technical expertise
- Custom manufacturing support including new chemical synthesis route finding
- Bovine Spongiform Encephalopathy (BSE) & Transmissible Spongiform Encephalopathies (TSEs) free certificates

A strong track record:

25 + years of experience synthesizing high quality excipients, including **custom manufacturing of proprietary lipids**. Benefit from our flexible manufacturing capacity allowing synthesis of gram scale samples up to multiple kilograms and tons.

Our team of experts has extensive experience in synthesis route scouting with scale up in mind to support you through your clinical development towards commercialization.



Our SAFC® portfolio with off-the-shelf lipid products:

Neutral lipids	Ionizable lipids	Cationic lipids	PEG lipids	Phospholipids	Others
Synthetic cholesterol²⁾ Cat. No. W004591 Cat. No. 104672	(R)-DODMA Cat. No. 500244	(R,S)-DOTAP CI Cat. No. 589692 (R)	mPEG 2k DSG Cat. No. 572495	DOPE Cat. No. 587762	Palmitic acid Cat. No. W50230
Isomeric mixture 1,3- and 1,2-GDO Cat. No. 588085	ALC-0315^{1,2)} Cat. No. 585807	(R)-DOTAP CI¹⁾ Cat. No. CH2900029	DMG PEG 2000 Cat. No. 578632	DPPC Cat. No. CH2900047	
Tripalmitin¹⁾ Cat. No. W50222		(S)-DOTAP CI¹⁾ Cat. No. CH2900030	ALC-0159¹⁾ Cat. No. 586054	DOPC³⁾ Cat. No. CH2900013	
		(R)-DOTMA CI Cat. No. 500249			

SAFC®

Pharma & Biopharma Raw
Material Solutions

- ¹⁾ Indication or license restriction.
²⁾ Dual sourcing capabilities.
³⁾ Upon request, please contact us.

Didn't find what you're looking for?

Contact us to discuss custom manufacturing of alternative lipid solutions to meet your needs at: SigmaAldrich.com/mRNA-CTDMO-Contact

Learn more about our Millipore® CTDMO services here: SigmaAldrich.com/MilliporeCTDMOServices

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.



The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

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