

# Lipid Excipients for Drug Delivery

Product Catalogue



People make our name

	Product description			
Excipient name	Definition / description	Form	Melting point (°C)	HLB
Apifil®	PEG-8 beeswax	Pellets	59 - 70	9
Capryol® 90	Propylene glycol monocaprylate NF <sup>1</sup>	Liquid	/	5
Capryol® PGMC	Propylene glycol mono and dicaprylate NF $^{\rm 2}$	Liquid	/	6
Compritol® 888 ATO	Glycerol dibehenate EP / Glyceryl dibehenate NF / Glyceryl behenate Ch.P.	Powder	65 - 77	1
Compritol® 888 Pellets	Glycerol dibehenate EP / Glyceryl dibehenate NF / Glyceryl behenate Ch.P.	Pellets	65 - 77	1
Compritol® HD 5 ATO	Behenoyl polyoxyl-8 glycerides NF	Powder	60 - 67	5
Emulfree® Duo	Mixture of Propylene glycol monolaurate (type I) EP / NF, Ethylcellulose EP / NF and Propylene glycol isostearate	Liquid	/	6
Geleol™ Mono and Diglycerides NF	Glycerol monostearate 40-55 (type I) EP / Mono and diglycerides $NF$	Pellets	54 - 64	3
Geloil™ SC	Mixture of refined soybean oil EP / NF, glyceryl distearate EP / NF and polyglyceryl-3 dioleate NF	Viscous gel	/	5
Gelot™ 64	Mixture of glycerol monostearate EP / NF and PEG-75 stearate (type I) NF $% \mathcal{A}_{\mathrm{S}}$	Pellets	55.5 - 62.5	10
Gelucire <sup>®</sup> 43/01	Hard fat NF / EP / JPE	Pellets	42 - 46	1
Gelucire® 44/14	Lauroyl macrogol-32 glycerides EP / Lauroyl polyoxyl-32 glycerides NF / Lauroyl macrogolglycerides (32) Ch.P.	Block	42.5 - 47.5	11
Gelucire® 48/16	Macrogol-32 stearate (type I) EP / Polyoxyl-32 stearate (type I) NF	Pellets	46 - 50	12
Gelucire <sup>®</sup> 50/13	Stearoyl macrogol-32 glycerides EP / Stearoyl polyoxyl-32 glycerides NF	Pellets	46 - 51	11
Gelucire® 59/14	Mixture of Lauroyl Polyoxyl-32 glycerides EP / NF and PEG 6000 EP / NF	Pellets	57-62	14
Labrafac™ Lipophile WL 1349	Triglycerides medium-chain EP / Medium-chain triglycerides NF / Medium-chain fatty acid triglyceride JPE	Liquid	/	1
Labrafac™ MC60	Glycerol monocaprylocaprate (type I) EP Glyceryl Mono and Dicaprylocaprate NF <sup>3</sup>	Liquid	/	5
Labrafac™ PG	Propylene glycol dicaprylocaprate EP Propylene glycol dicaprylate/dicaprate NF	Liquid	/	1
Labrafil® M 1944 CS	Oleoyl macrogol-6 glycerides EP / Oleoyl polyoxyl-6 glycerides NF	Liquid	/	9
Labrafil® M 2125 CS	Linoleoyl macrogol-6 glycerides EP / Linoleoyl polyoxyl-6 glycerides NF	Liquid	/	9
Labrafil® M 2130 CS	Lauroyl macrogol-6 glycerides EP / Lauroyl polyoxyl-6 glycerides NF	Block	33 - 38	9
Labrasol®	Caprylocaproyl macrogol-8 glycerides EP Caprylocaproyl polyoxyl-8 glycerides NF	Liquid	1	12
Labrasol® ALF	Caprylocaproyl macrogol-8 glycerides EP Caprylocaproyl polyoxyl-8 glycerides NF	Liquid	1	12
Lauroglycol™ 90	Propylene glycol monolaurate (Type II) EP / NF	Liquid	/	3
Lauroglycol™ FCC	Propylene glycol monolaurate (Type I) EP / NF	Liquid	/	5
Maisine® CC	Glycerol monolinoleate EP / Glyceryl monolinoleate NF	Liquid	/	1
Ovucire® range	Mixture of Hard fat EP / NF / JPE with additives	Pellets	32 - 34	/
Peceol™	Glycerol mono-oleate (type 40) EP / Glyceryl monooleate (type 40) NF	Liquid	/	1
Plurol® Diisostearique	Triglycerol diisostearate EP / Polyglyceryl-3 diisostearate NF	Liquid	/	4.5
Plurol <sup>®</sup> Oleique CC 497	Polyglyceryl-3 dioleate NF	Liquid	/	3
Precirol <sup>®</sup> ATO 5	Glycerol distearate (type I) EP / Glyceryl distearate NF	Powder	50 - 60	2
Sedefos™ 75	Mixture of triceteareth-4 phosphate and ethylene glycol stearate EP / NF/ JPE (and) diethylene glycol stearate EP / NF / JPE	Pellets	47 - 52	10
Suppocire <sup>®</sup> range	Hard fat EP / NF / JPE/ Ch.P.	Pellets	33 - 45	/
Tefose <sup>®</sup> 1500	Mixture of PEG-6 stearate (type I) NF and PEG-32 stearate (type I) NF	Block	40.4 - 44.4	10
Tefose® 63	Mixture of PEG-6 stearate (type I) NF and Ethylene glycol palmitostearate EP / NF / JPE and PEG-32 stearate (type I) NF	Block	46 - 53	9.5
Transcutol® HP	Highly purified diethylene glycol monoethyl ether EP / NF	Liquid	/	/
Transcutol® P	Highly purified diethylene glycol monoethyl ether EP / NF	Liquid	/	/

<sup>1</sup> May also be labeled as USP Propylene glycol monocaprylate (Type II) until December 1, 2026
 <sup>2</sup> May also be labeled as USP Propylene glycol monocaprylate (Type I) until December 1, 2026
 <sup>3</sup> May also be labeled as USP Glyceryl monocaprylocaprate (Type I) until May 1, 2025

Functionalities and routes of administration													
Route of administration			Or	ral			Topical						Rectal
Functionality	Bioavailability enhancement	Sustained release	Lubricant	Taste-masking	API protection	Vehicle for capsule	Emulsifier	Oil stabilizing agent	Thickener	Solubilizer	Penetration enhancer	Oily vehicle	Vehicle
Apifil®							٠						
Capryol® 90	•			•		•				٠	•		
Capryol® PGMC	•									•	•		
Compritol® 888 ATO		•	•		٠								
Compritol® 888 Pellets				•					٠				
Compritol® HD 5 ATO			٠										
Emulfree® Duo						•		•		•			
Geleol™ Mono and Diglycerides NF		•		•	٠				٠				
Geloil™ SC					٠	•							
Gelot™ 64							٠						
Gelucire® 43/01					٠				٠				
Gelucire® 44/14	•												
Gelucire® 48/16	•												
Gelucire® 50/13	•												
Gelucire® 59/14	•												
Labrafac™ Lipophile WL 1349	•					•				٠		•	
Labrafac™ MC60	•												
Labrafac™ PG				•						٠		•	
Labrafil® M 1944 CS	•									•			
Labrafil® M 2125 CS	•									•			
Labrafil® M 2130 CS										•			
Labrasol®										٠	٠		
Labrasol® ALF	•												
Lauroglycol™ 90	•									٠	•		
Lauroglycol™ FCC										•	•		
Maisine <sup>®</sup> CC	•			•		•							
Ovucire® range													•
Peceol™	•									٠		•	
Plurol® Diisostearique				•			٠						
Plurol® Oleique CC 497	•			•						٠	•		
Precirol <sup>®</sup> ATO 5		•	•	•									
Sedefos™ 75							•						
Suppocire <sup>®</sup> range													•
Tefose® 1500				•			•						
Tefose® 63							•						
Transcutol® HP	•												
Transcutol <sup>®</sup> P										•	•		
		: :		:	:	:		: :		:	: :		

Regulatory information and precedence of use													
Excipient name	NF Pharmacopoeia	EP Pharmacopoeia	Pharmacopoeia	US Drug Master File	Chinese Bundling Review	Handbook of Pharmaceutical Excipients	Precedence of use of the chemical entity (Examples; not exhaustive)						
	NF Pha	EP Pha	JPE Ph	US Drui	Chinese	Handbo Pharma	<b>GRAS Status</b>	FDA IID	USA / Canada	Europe Japan		Other countries	
Apifil®										Topical		Topical	
Capryol <sup>®</sup> 90	•	•1		•		•		•	Oral / Topical	Oral / Topical / Veterinary	Oral	Topical / Veterinary	
Capryol <sup>®</sup> PGMC	٠			•		•1				Oral OTC			
Compritol® 888 ATO	•	٠		•	•	•	•	•	Oral	Oral / Ocular	Oral	Oral	
Compritol® 888 Pellets	٠	٠		•	•	•	•	•		Topical / Vaginal		Topical / Rectal / Vaginal	
Compritol® HD 5 ATO	•								Oral OTC	Oral OTC		Oral OTC	
Emulfree <sup>®</sup> Duo													
Geleol™ Mono and Diglycerides NF	•	•			•	•	•	•	Oral / Topical / Rectal / Vaginal	Oral / Topical / Vaginal	Oral / Topical	Oral / Topical	
Geloil™ SC	٠					•		•	Dietary supplements			Dietary supplements	
Gelot™ 64	٠					•		•	Topical	Topical		Topical	
Gelucire <sup>®</sup> 43/01	٠	٠	•	•		•		•	Oral				
Gelucire® 44/14	٠	٠		•		•		•	Oral	Oral	Oral	Oral / Nasal	
Gelucire® 48/16	٠	٠				•			Topical	Oral / Topical			
Gelucire® 50/13	٠	٠		•		•		•	• Oral Oral				
Gelucire® 59/14	٠	٠											
Labrafac™ Lipophile WL 1349	•	•	•			•		•	Oral / Topical / Ophtalmic / Sublingual	Oral / Topical / Vaginal / Ophtalmic / Sublingual / Veterinary	Oral / Topical	Oral / Topical / Ophtalmic / Veterinary	
Labrafac™ MC60	•	•				•	•	•	Oral / Topical	Oral / Topical		Oral	
Labrafac™ PG	•	•				•				Oral		Veterinary	
Labrafil® M 1944 CS	•	•		•	•	•		•	Topical / Rectal / Vaginal / Oral / Topical / Rectal / Nasal / Veterinary Vaginal / Nasal / Veterinary			Oral / Topical / Rectal / Vaginal	
Labrafil® M 2125 CS	•	•		•		•		•	Oral / Topical / Rectal Oral / Topical / Rectal Oral Oral		Oral	Oral	
Labrafil® M 2130 CS	•	•		•		•		•			Topical		
Labrasol®	•	•		•	•	•		•			Topical / Transdermal		
Labrasol <sup>®</sup> ALF	•	٠		•	•	•		•	• Oral Oral Oral		Oral		
Lauroglycol™ 90	•	•		•		•		•	• Oral Oral Oral		Oral / Topical / Nasal		
Lauroglycol™ FCC	•	•		•	•	•		•	Oral Oral / Topical		Oral		
Maisine <sup>®</sup> CC	•	•		•	•	•	•	•	Oral     Oral     Oral		Oral		
Ovucire <sup>®</sup> range	●2	●2				•2		•	Vaginal Vaginal		Vaginal		
Peceol™	•	•		•	•	•	•	•	Oral / Topical / Transdermal/     Dietary supplements     Oral / Topical / Transdermal     Oral		Oral	Oral / Topical	
<b>Plurol® Diisostearique</b>	•	•							Topical				
Plurol <sup>®</sup> Oleique CC 497	•			•	•			•	Oral / Vaginal	Oral		Oral / Vaginal	
Precirol <sup>®</sup> ATO 5	•	•		•		•	•	Oral Oral Oral		Oral	Oral		
Sedefos™ 75								•		Topical			
Suppocire <sup>®</sup> range	●2	●2	•2	•	•	•		Rectal / Vaginal     Rectal / Vaginal     Rectal / Vaginal		Rectal / Vaginal			
Tefose <sup>®</sup> 1500	•			•		•		Topical Topical / Rectal					
Tefose <sup>®</sup> 63	•				•	•						Topical / Rectal / Vaginal	
Transcutol® HP	•	•		•	•	•						Oral	
Transcutol® P	•	•		•	•	•		•	Topical / Transdermal	Topical / Transdermal / Vaginal		Topical / Transdermal	

# Lipid Excipients for Drug Delivery

#### About Gattefossé

Since 1880, Gattefossé develops innovative lipid excipients for oral solubilization, bioavailability enhancement, sustained release, lubrication, API protection and taste-masking. We provide solubilizers and skin penetration enhancers, emulsifiers and consistency agents for improved topical and transdermal formulations. Gattefossé has also dedicated ranges for the veterinary and the nutraceutical markets. Every product is designed with utmost attention to safety, quality, and performance consistency. As part of Gattefossé offer, technical and regulatory support is provided by fully trained experts to accelerate customers drug development programs.

#### **Functional lipid excipients**

Our lipid excipients are manufactured using vegetable oils (including corn, apricot kernel or coconut oil), a wide array of plant-derived fatty acids, and alcohols such as fatty alcohols, polyethylene glycol (PEG), propylene glycol (PG) and polyglycerol.

Three reactions are commonly utilized to manufacture our excipients:

- esterification, a reaction between an acid and an alcohol leading to an ester and water
- transesterification, a reaction between an ester and an alcohol to produce a different ester and alcohol
- interesterification, a reaction between esters to produce new esters

Depending on the used raw materials, these reactions enable the manufacture of solid, semi-solid, or liquid excipients. The fatty-acid chain length and composition in terms of fatty alcohols and mono-, di- and triglycerides, impact the end-product physicochemical and functional properties. Our oleochemists are able to develop functional pharmaceutical excipients having targeted properties through the selection of raw materials, the design and control of the synthesis reaction.

# **Manufacturing quality**

Our manufacturing sites are ISO certified by SGS (9001 version 2015) and follow IPEC Good Manufacturing Practices (GMP) guidelines. Production processes comply to international standards and follow a rigorous Quality Management System. We have obtained the GMP certificate of inspection from ANSM (Agence nationale de sécurité du médicament et des produits de Santé – the French health authority).

# Technical centres of excellence

Our technical centres of excellence in France, India, China and the USA are at your service to provide technical support and formulation feasibility assessment to meet the rapidly evolving drug delivery challenges. Our key strengths are in providing formulation development support for solubilization, oral bioavailability enhancement and sustained release applications. For topicals, we advise on difficult to formulate drugs, resolve stability issues and improve texture and sensoriality. For transdermal delivery, our expertise in Franz cells diffusion system enables to select the most appropriate penetration enhancers. For rectal and vaginal dosage forms, we help customers optimize formulations for performance and manufacturability.

# **Corporate Social Responsibility**

Environmental, social, and societal issues have always been part of the Gattefossé culture. Our Corporate Social Responsibility vision (CSR) is to lead together the transition to a business model that combines sustainable growth and general interest. In 2021 our CSR approach was granted the highest level of recognition "Platinum", with a score of 74/100, ranking Gattefossé in the TOP 1% of EcoVadis (CSR performance rating platform) evaluations. In 2021, Gattefossé also obtains the ISO 14001:2015 certification for its main production site in Saint-Priest (France).

Apifil<sup>®</sup>, Capryol<sup>®</sup>, Compritol<sup>®</sup>, Emulfree<sup>®</sup>, Gelucire<sup>®</sup>, Labrafil<sup>®</sup>, Labrasol<sup>®</sup>, Maisine<sup>®</sup>, Ovucire<sup>®</sup>, Plurol<sup>®</sup>, Precirol<sup>®</sup>, Suppocire<sup>®</sup>, Tefose<sup>®</sup> and Transcutol<sup>®</sup> are registered trademarks of Gattefossé.

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REFERE





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