

# Lipid-Based Excipients for Pharmaceutical Manufacturing

BASF offers the widest range of IPEC-GMP lipid-based excipients, suitable for topical and oral drug formulations. We are committed to providing high quality products supported by best-in-class regulatory, quality, and technical teams. With both sustainability and quality at the forefront of our diverse portfolio, we offer products that are not only 100% RSPO certified (Roundtable on Sustainable Palm Oil), but also EXCiPACT® certified to support the evolving values in the marketplace. Our lipid-based pharmaceutical excipients are certified Kosher and Halal\*.

## Kolliphor® Product Line

The Kolliphor® product line is a broad portfolio of emulsifiers, wetting agents, solubilizers, and cream bases that are used in a variety of oral and topical pharmaceutical applications.

	Product name	Chemical/ Compendial name	Product size	Article number	Quality	Function	Description
E	Kolliphor® CS 12	Macrogol cetostearyl ether 12	20kg	50489196	Ph. Eur.	Emulsifier	Nonionic emulsifier used in oil-water emulsions.
E	Kolliphor® CS 20	Macrogol cetostearyl ether 20	25kg	50253257	Ph. Eur., USP	Emulsifier	Nonionic emulsifier used in oil-water emulsions.
E	Kolliphor® CS A	Mixture of cetostearyl alcohol and sodium cetostearyl sulfate	20kg	50253281	Ph. Eur.	Emulsifier	Anionic emulsifier and consistency factor combination for creams and lotions. Can also be used as a self-emulsifying wax.
E	Kolliphor® CSL	Mixture of cetostearyl alcohol, sodium lauryl sulfate, and sodium cetostearyl sulfate	20kg	50253856		Emulsifier	Mixture of emulsifier and waxes for use in self-emulsifying and consistency building.
E	Kolliphor® CSS	Sodium cetostearyl sulfate	12kg	50253269	Ph. Eur.	Emulsifier	Anionic emulsifier.
E	Kolliphor® PS 20	Polysorbate 20	190kg	50438811	Ph. Eur., USP	Solubilizer	Nonionic solubilizer and emulsifier used in a variety of applications.
E	Kolliphor® PS 60	Polysorbate 60	190kg	50278844	Ph. Eur., USP, JP	Solubilizer	Nonionic solubilizer and emulsifier used in a variety of applications.
E	Kolliphor® PS 80	Polysorbate 80	190kg	50439067	Ph. Eur., USP	Solubilizer	Nonionic solubilizer and emulsifier used in a variety of applications.
E	Kolliphor® SLS	Sodium lauryl sulfate	25kg	50253852	Ph. Eur., USP, JP	Wetting agent	Wetting agent, emulsifier, solubilizer used for a variety of pharmaceutical applications.
E	Kolliphor® SLS Fine	Sodium lauryl sulfate	15kg	50253853	Ph. Eur., USP, JP	Wetting agent	Wetting agent used for tablet making. Fine particle size reduces dissolution time.

\*Lorol® C16 NVT is neither Kosher nor Halal certified. Cutina® LE is solely Kosher certified.

E EXCiPACT® certified    R (RSPO (Roundtable on Sustainable Palm Oil) certified)

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## Kollicream® Product Line

The Kollicream® product line is comprised of multi-functional solvents and emollients. These excipients enhance solubilization and skin penetration of some pharmaceuticals while offering a relatively benign mildness profile.

	Product name	Chemical/ Compendial name	Product size	Article number	Quality	Function	Description
E	Kollicream® 3 C	Cocoyl caprylocaprate	800kg 175kg	50268489 50363006	Ph. Eur.	Solvent	Extremely mild solvent for lipophilic drugs that enhances skin penetration.
E	Kollicream® CP 15	Cetyl palmitate 15	20kg	50253253	Ph. Eur.	Emollient	Solid, slow spreading solvent for lipophilic drugs.
E	Kollicream® DO	Decyl oleate	175kg	50253252	Ph. Eur.	Solvent	Solvent for lipophilic drugs with medium spreadability. Also enhances skin penetration.
E	Kollicream® IPM	Isopropyl myristate	850kg 175kg	50264409 50253267	Ph. Eur., USP	Solvent	Fast spreading solvent for lipophilic drugs. Has a light and fresh feeling while enhancing skin penetration.
E	Kollicream® OA	Oleyl alcohol	850kg 175kg	50253266 50253265	Ph. Eur., USP	Solvent	Solvent for lipophilic drugs with medium spreadability. Also enhances skin penetration.
E	Kollicream® OD	Octyldodecanol	175kg	50253259	Ph. Eur., USP	Solvent	Solvent for lipophilic drugs with medium spreadability. Also enhances skin penetration and is effective at a wide pH range.

## Kolliwax® Product Line

The Kolliwax® product line is an extensive portfolio of structuring agents that provide formulation stability. These excipients can be used in the development of numerous oral and topical dosage forms.


	Product name	Chemical/ Compendial name	Product size	Article number	Quality	Function	Description
E	Cutina® LE	Glyceryl stearate and sodium cetearyl sulfate	25kg	50207228			
E	Kolliwax® S	Stearic acid 50	25kg	50253532	Ph. Eur., USP, JP	Consistency factor	Structure-building consistency factor with dry feel.
E	Kolliwax® S Fine	Stearic acid 50	25kg	50253810	Ph. Eur., USP, JP	Lubricant	Lipophilic lubricant suitable for sensitive APIs.
E	Kolliwax® CA	Cetyl alcohol	25kg	50253459	Ph. Eur., USP	Consistency factor	Structure-building consistency factor for semi-solids.
E	Kolliwax® CSA 50	Cetostearyl alcohol	25kg	50253501	Ph. Eur., USP, JP	Consistency factor	Structure-building consistency factor for semi-solids.
E	Kolliwax® CSA 70	Cetostearyl alcohol	25kg	50253504	Ph. Eur.	Consistency factor	Structure-building consistency factor for semi-solids.
E	Kolliwax® GMS II	Glycerol monostearate	25kg	50264282	Ph. Eur., USP	Co-emulsifier	Low HLB surfactant used for stabilization of surfactant phases and emulsion droplets.
	Kolliwax® HCO*	Hydrogenated castor oil	20kg	50487016	Ph. Eur., USP, JP	Filler & Pore Former	Extrudable lipophilic matrix former for granules, pellets and tablets. Lipophilic pore former for monolithic tablets and sustained release coatings.
E	Kolliwax® MA	Myristyl alcohol	20kg	50375472	USP	Consistency factor	Consistency factor with low melting point and soft sensory effect.
E	Kolliwax® SA	Stearyl alcohol	25kg	50253503	Ph. Eur., USP, JP	Lubricant	Lipophilic lubricant suitable for sensitive acidic APIs.
E	Kolliwax® SA Fine	Stearyl alcohol	25kg	50284249	Ph. Eur., USP, JP	Lubricant	Lipophilic lubricant suitable for sensitive acidic APIs.
	Lorol® C 16 NVT	Cetyl alcohol	20kg	50210317			Mixture of C16 and C18 fatty alcohols

\*Kolliwax® HCO, which is based on castor oil, is fully IPEC-GMP. As Kolliwax® HCO is not produced in Duesseldorf-Holthausen, it is not EXCiPACT® certified.

E EXCiPACT® certified RSPO (Roundtable on Sustainable Palm Oil) certified




## Kollisolv® Product Line

Functioning as solubilizers, plasticizers, lubricants, emollients, and skin penetration enhancers, the Kollisolv® product line is composed of versatile solvents. Kollisolv® solvents are ideal for both oral and topical applications.

	Product name	Chemical/ Compendial name	Product size	Article number	Quality	Function	Description
E	Kollisolv® GTA	Triacetin	235kg	50253533	Ph. Eur., USP	Solvent	Versatile solvent miscible in water or oil.
E 	Kollisolv® MCT 70	Medium chain triglycerides	190kg	50253413	Ph. Eur., USP	Solvent	Oily solvent for some lipophilic drugs. Film former for skin delivery.
	MCT 70 BR	Medium chain triglycerides	190kg	50653543		Solvent	Oily solvent for some lipophilic drugs. Film former for skin delivery. For sale in South American markets only. Complies to Brazilian GMP standards.

## Novata® Product Line

The Novata® product line functions as structuring agents for anhydrous formulations. These matrix builders are applicable in oral, topical, and rectal dosage forms.

	Product name	Chemical/ Compendial name	Product size	Article number	Quality	Function	Description
E 	Novata® B PH	Hard fat	25kg	50736109	Ph. Eur.	Consistency factor	Lipidic matrix and viscosity enhancer.
E 	Novata® BC PH	Hard fat	25kg	50737147	Ph. Eur.	Consistency factor	Lipidic matrix and viscosity enhancer.
E 	Novata® BCF PH	Hard fat	25kg	50736956	Ph. Eur.	Consistency factor	Lipidic matrix and viscosity enhancer.

E EXCiPACT® certified  RSPO (Roundtable on Sustainable Palm Oil) certified





## Taking Quality to the Next Level

### BASF lipid-based excipients are now EXCiPACT® certified

Auditing suppliers for GMP/GDP is an accepted best practice and may be required for pharmaceutical manufacturers under some national laws. Functioning as a third party, EXCiPACT asbl is a non-profit organization that owns and manages oversight of such an independent, high-quality certification scheme which is available to pharmaceutical excipient manufacturers and distributors worldwide. As an EXCiPACT® certificate holder, BASF is a reliable source that offers access to audit reports and certificates to simplify the supplier qualification process.

#### EXCiPACT® benefits include:

- ✓ Saves you money through the reduction of supplier audits, travel, and administration costs
- ✓ Is provided by approved third-party certification bodies
- ✓ Reduces audit burden and cost
- ✓ Is supported by key regulatory bodies
- ✓ Helps excipient users identify qualified suppliers



## It's Time to Think about Sustainable Sourcing

### BASF introduces the first RSPO-certified lipid-based excipients for the pharmaceutical industry

A key renewable raw material for numerous pharmaceutical excipients is palm kernel oil (PKO) and its respective derivatives. The ubiquitous use of these materials across industry has contributed significantly to deforestation, loss of biodiversity and climate change. As a result, there is widespread concern about these challenges among retailers, NGOs, investors and consumers. Take advantage of BASF lipid-based products certified by the Roundtable on Sustainable Palm Oil (RSPO) and align your company and products with the strong sustainability values evolving in the marketplace.

#### Join BASF in committing to sustainable sourcing for lipid-based pharmaceutical excipients

- ✓ Contribute significantly to your own sustainable sourcing efforts
- ✓ Same high-quality, compendial lipid-based products with no physical or chemical changes
- ✓ RSPO-certified lipid-based products
- ✓ Certificate numbers provided with every produced and delivered batch
- ✓ Join BASF as part of RSPO to market your own products as RSPO-certified

#### RSPO offers the global certification of palm oil

- ✓ 4,107 members in 92 countries
- ✓ Certifies sustainability practices of palm plantations
- ✓ Certifies the integrity of the supply chain to you



## Exceptional Quality & Regulatory Support



The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high-quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality-related questions.

A regional footprint secures quick and regional-specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations, we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

Access to standard quality and regulatory documentation is now more efficient than ever. Retrieve your documents 24/7 from your WorldAccount or sign-up for new RegXcellence®, your free online Quality & Regulatory Assistant that provides a unified platform for compliance documents, filing assistance and audit information.



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