



Life Science

Product Overview

Excipients
Derived from Nature | Driven by Innovation

Edition
October 2025



Reliable excipients for the pharmaceutical industry.

Quality, safety, and reliability are essential in pharmaceutical development.

Our range of high-quality excipients, offered under the brands Hedjuvan and ENHEX, is based on our guiding principle of “Excipients - Derived from Nature | Driven by Innovation”. With decades of experience and a deep understanding of naturally based raw materials, we offer solutions that meet very high standards and continuously strive for innovative solutions to meet market needs.

Every product in our portfolio is extensively tested so you can trust in proven quality. Our excipients support you in developing innovative medicines to contribute to better health for humanity.

Rely on our expertise and product solutions to successfully bring your pharmaceutical products to market. With our Hedjuvan and ENHEX brands, we are harnessing the power of nature for your future.



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KLK OLEO Life Science

Excipients - Derived from Nature | Driven by Innovation

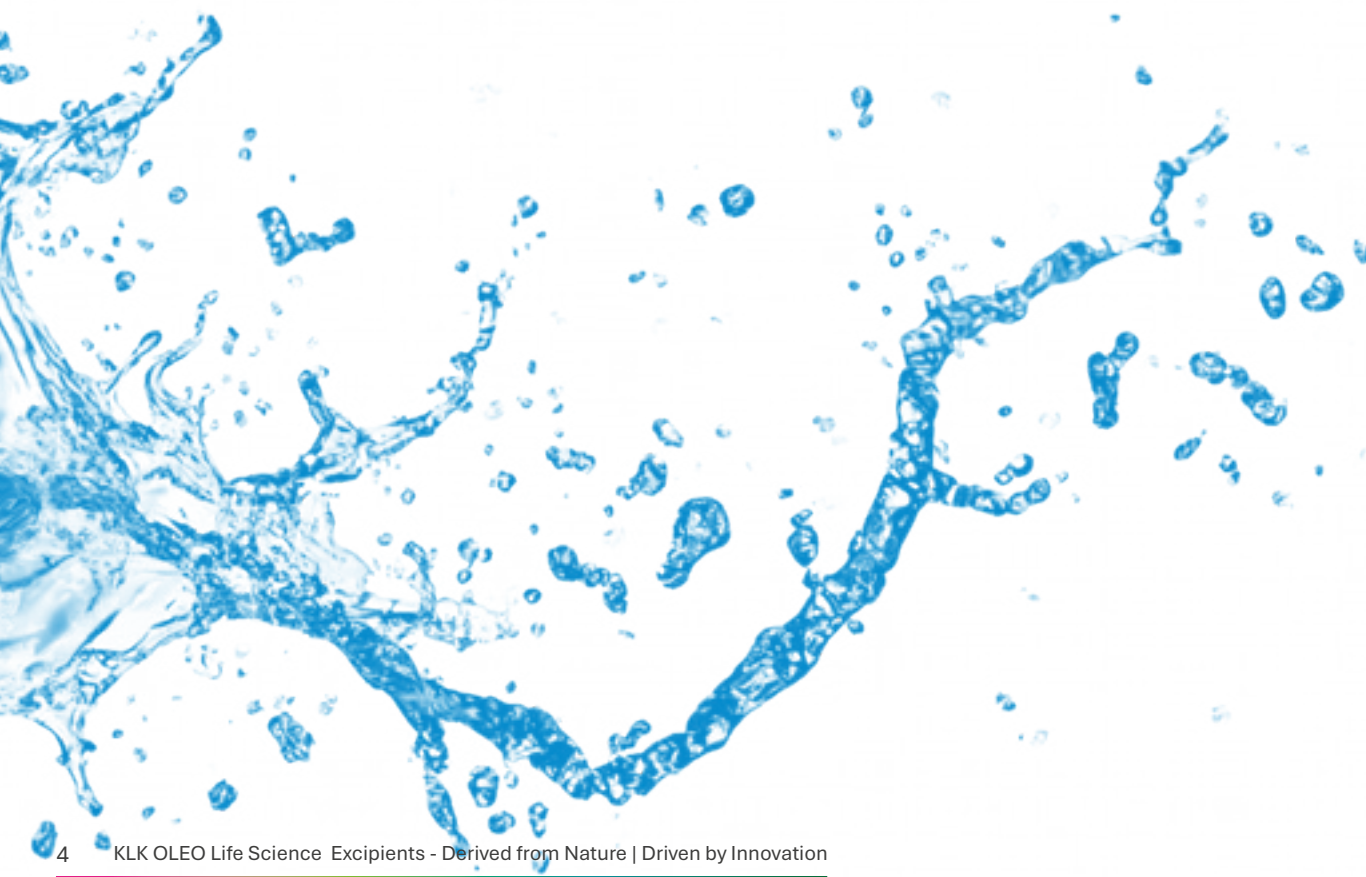
KLK OLEO Life Science is your preferred manufacturer of pharmaceutical excipients and processing ingredients to enhance drug product performance, solubility, and stability. As part of KLK OLEO, a global leader in oleo chemistry, we built on a strong foundation and international network. This allows us to support your sites in many countries around the world. Delivering outperforming chemicals for the pharmaceutical industry, manufactured in the heart of Europe.

Whether you require portfolio excipients or customised chemicals and blends, KLK OLEO Life Science is your partner of choice. Our highly experienced scientists in our R&D Centers support you in whatever challenge, as we develop and deliver tailored solutions to meet your needs. Together enabling drugs that make a difference.

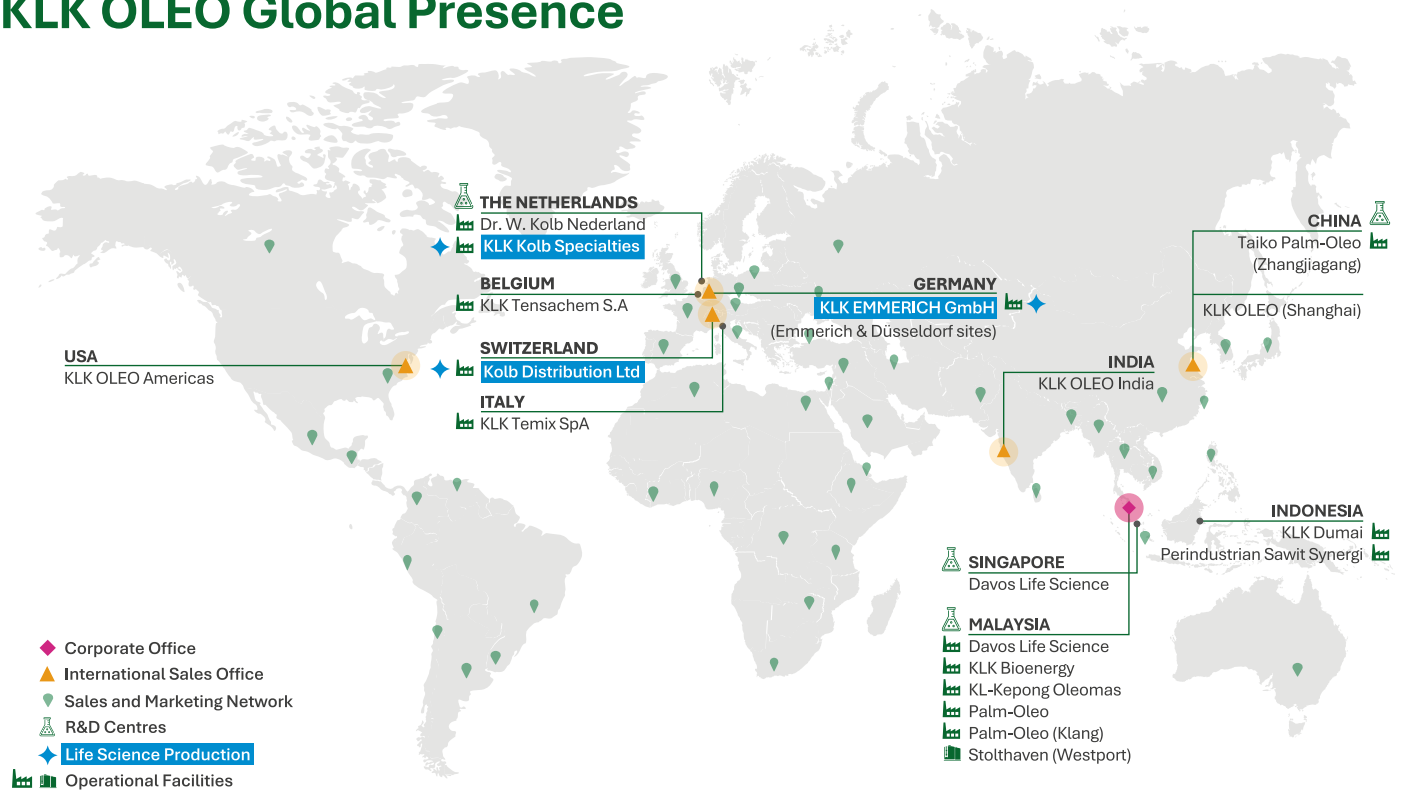
Dedicated to human welfare, we strive for manufacturing excipients under highest quality and safety standards. We provide our customers with comprehensive regulatory documentation and in-depth knowledge to help applying our products the best way possible.

As a responsible company, we actively address today's global challenges. Sustainability is in the center of our daily work, and we constantly thrive at improving ourselves and reducing emissions. With our bio-circular portfolio of low carbon footprint products, we are at the forefront of active contribution to a better tomorrow.

KLK OLEO Life Science is your trusted partner for pharmaceutical excipients. Rely on us so that you can focus on what matters most – patient's health.



KLK OLEO Global Presence



16 Operating Facilities | 4 R&D Centres | 6 International Sales Offices | Supplying over 120 Countries

Trusted Partner for Life Science Solutions

Life Science providers and professionals rely on us for more than just products - they choose a partner committed to quality, reliability, and service:

Proven Manufacturing Expertise

- Decades of experience in producing pharmaceutical-grade materials with high batch-to-batch consistency.

European Quality - Made in Switzerland, Germany and the Netherlands

- Manufacturing excellence rooted in three of the world's most trusted production hubs.

Customer-Focused Service

- We work closely with our partners to deliver tailored solutions and responsive support.

High Standards, High Trust

- Our products meet stringent quality and safety requirements.

Transparent Documentation

- Comprehensive product information to support regulatory compliance.

Sustainable Product Range

- Many of our offerings are based on renewable raw materials, supporting KLK OLEO's broader sustainability goals.

RSPO Supply Chain Certified

- Ensuring responsible sourcing and traceability for palm-based ingredients.

Reliable, backward integrated Supply Chain

- Large production capacities and a transparent supply chain ensure consistent availability.
- Control over key raw materials guarantees reliability and continuity - critical for pharmaceutical operations.

Certifications – Quality and Sustainability

We uphold high industry standards, supported by globally recognised certifications that demonstrate our commitment to quality, sustainability, and ethical practices.

Overview of the KLK OLEO Life Science manufacturing sites

KLK OLEO Life Science manufacturing site	Applied Certification Standards												Product types	
	ISO 9001	ISO 14001	ISO 22000	FSSC 22000	ISO 45001	ISO 50001	EXCiPACT™ GMP/GDP	Ecovadis	ISCC PLUS	RSPO	Kosher	Halal	Excipients	Other processing ingredients used in pharmaceutical industry
Emmerich (Germany)	X	X	X		X	X	X	Bronze	n.a.	X	X	X	X	X
Düsseldorf (Germany)	X	X		X		X	X	Bronze	n.a.	X	X	X	X	X
Hedingen (Switzerland)	X	X			X	X	X	Platinum	X	X	X	X	X	X
Delden (Netherlands)	X	X			X	X		Silver	X	X	X	X		X

Quality at KLK OLEO Certified Quality You Can Trust

In pharmaceutical manufacturing, quality is not optional - it's essential. That's why our excipients are backed by a comprehensive portfolio of quality certificates that reflect our unwavering commitment to safety, compliance, and performance.

Each site is regularly audited and certified to meet international standards, including ISO 9001, ISO 140001 and ISO 50001.

All listed excipients' manufacturing processes are certified according to EXCiPACT™ standards and pharmacopoeial compliance. These certifications are more than just documents, they are a reflection of our dedication to purity, consistency, and regulatory reliability.

With full traceability and comprehensive documentation including Certificates of Analysis, technical documents, and various statements you can trust that our excipients are produced with integrity and precision.

Our Certifications



ISO CERTIFICATIONS:

ISO 9001 - Quality management system
 ISO 14001 - Environmental management system
 ISO 22000 - Food Safety management system
 ISO 45001 - Occupational health and safety management
 ISO 50001 - Energy management system

EXCiPACT™

EXCiPACT™ asbl is a non-profit organisation that owns and manages oversight of an independent, high quality, third party Certification Program. This international certification program is aimed at manufacturers and suppliers of pharmaceutical excipients. The program ensures increased transparency and safety in pharmaceutical production as well as improved quality of excipients along the supply chain. KLK OLEO Life Science manufactures all ENHEX and Hedjuvan excipients according to EXCiPACT™ GMP/GDP certified processes.

FSSC 22000

FSSC 22000 is an internationally recognised food safety certification system based on the ISO 22000 standard and recognised by the Global Food Safety Initiative (GFSI). It is a system that combines the requirements of ISO 22000 with specific preventive programs as well as additional requirements to ensure that companies comply with the highest standards of food safety.

HALAL / KOSHER

All of the KLK OLEO Life Science pharmaceutical grade excipients are Kosher and Halal compliant products. Please contact us to learn more about the Kosher and Halal status of our products.

Sustainability

KLK OLEO is committed to developing natural-based and low carbon footprint products. To achieve this, the company supports several sustainable initiatives for sourcing raw materials. These efforts are driven by customer demand for environmentally friendly solutions and align with KLK OLEO's broader sustainability goals, including reducing greenhouse gas emissions and adhering to strict environmental standards.



Roundtable on Sustainable Palm Oil (RSPO)

Established in 2004, the RSPO is a global, non-profit, multi-stakeholder initiative dedicated to sustainable palm oil. It unites over 4,000 members worldwide, representing all segments of the palm oil supply chain. These members include growers like KLK, processors, traders, consumer food manufacturers, retailers, financial institutions, and environmental and social non-governmental organisations from various countries involved in palm oil production and usage.

RSPO 1106058

KLK was a founding member of the Roundtable on Sustainable Palm Oil (RSPO) in 2004 and played a significant role in developing a comprehensive Sustainability Policy in 2014.

The Palm Oil Supply Chain



ISCC PLUS

ISCC PLUS is a sustainable certification scheme for bio-based, renewable and circular raw materials. Based on ISCC PLUS certification, KLK OLEO Life Science offers excipients based on alkoxylation process with a drastically reduced Product Carbon Footprint (PCF).

Together for Sustainability (TfS)

KLK OLEO Europe supports the goals of Together for Sustainability (TfS), a global initiative dedicated to advancing sustainability across the chemical supply chain. All KLK OLEO Europe sites are regularly audited using TfS criteria, which are based on internationally recognised ESG standards.

These assessments help drive transparency, responsible sourcing, and continuous improvement throughout our operations and supply network.

EcoVadis

KLK OLEO partners with EcoVadis, a globally recognised platform for assessing corporate sustainability across key areas such as environmental impact, labour and human rights, ethics, and procurement. Through this collaboration, KLK OLEO demonstrates its commitment to transparency, continuous improvement, and responsible business practices throughout its supply chain.



Hedjuvan Circular - Sustainable Innovation, Proven Quality

In our Hedjuvan Circular line, sustainability and quality work together. Products are manufactured at our Swiss site under the same stringent standards as conventional pharmaceutical excipients marketed under the “Hedjuvan” brand.

By incorporating bio-circular ethylene oxide (EO) into formulations, the PCF is significantly reduced keeping all other product parameters. The mass balance approach ensures no effective change in raw material chemical composition.

Product Carbon Footprint Overview

Product Family	Product Name	Compendial Name	Approximate reduction of the total Global Warming Potential (GWP) (incl. CO2 emissions and removals) by Circular grade.	Approximate content of renewable raw materials (incl. bio-circular EO)
Polysorbates	Hedjuvan-PS 20	Polysorbate 20	75%	▲ 25% 100% ▲
	Hedjuvan-PS 60	Polysorbate 60	66%	▲ 35% 100% ▲
	Hedjuvan-PS 80	Polysorbate 80	96%	▲ 35% 100% ▲
Macrogols / Polyethylene Glycols	Hedjuvan-MG 300	Macrogol 300 / Polyethylene Glycol 300	66%	▲ 0% 65% ▲
	Hedjuvan-MG 400	Macrogol 400 / Polyethylene Glycol 400	75%	▲ 0% 75% ▲
	Hedjuvan-MG 600	Macrogol 600 / Polyethylene Glycol 600	84%	▲ 0% 80% ▲
	Hedjuvan-MG 1000	Macrogol 1000 / Polyethylene Glycol 1000	87%	▲ 0% 90% ▲
	Hedjuvan-MG 1500	Macrogol 1500 / Polyethylene Glycol 1500	85%	▲ 0% 95% ▲
	Hedjuvan-MG 3350	Macrogol 3350 / Polyethylene Glycol 3350	90%	▲ 0% 97% ▲
	Hedjuvan-MG 4000	Macrogol 4000 / Polyethylene Glycol 4000	91%	▲ 0% 98% ▲
Others	Hedjuvan-PD9	Macrogol Lauryl Ether 9 EO	80%	▲ 0% 70% ▲

▲ Standard grade | ▲ Circular grade



Product Overview

Monograph title (Ph. Eur.)	Product	Tested according to	Production standard	Page
GLYCERIN				P. 12
GLYCEROL	ENHEX G 99.8 PH	Ph. Eur., USP-NF; Meets requirements: JP, ChP, BP**	EXCiPACT™ GMP/GDP	
GLYCEROL (85 per cent)	ENHEX G 86 PH	Ph. Eur.; Meets requirements: BP**	EXCiPACT™ GMP/GDP	
GLYCEROL (85 per cent)	ENHEX G 86 XPS	Ph. Eur.; Meets requirements: JP, BP**	EXCiPACT™ GMP/GDP	
MACROGOLS / POLYETHYLENE GLYCOLS				P. 14
MACROGOL 300	Hedjuvan-MG300	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL 400	Hedjuvan-MG400	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL 600	Hedjuvan-MG600	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL 1000	Hedjuvan-MG1000	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL 1500	Hedjuvan-MG1500	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL 3350	Hedjuvan-MG3350	Ph. Eur.	EXCiPACT™ GMP	
MACROGOL 4000	Hedjuvan-MG4000	Ph. Eur., USP-NF	EXCiPACT™ GMP	
MACROGOL LAURYL ETHER				P. 16
MACROGOL LAURYL ETHER	Hedjuvan-PD9	Ph. Eur.	EXCiPACT™ GMP	
MCT OIL (CAPRYLIC/CAPRIC TRIGLYCERIDE)				P. 17
TRIGLYCERIDES, MEDIUM-CHAIN	ENHEX MCT 64	Ph. Eur., *	EXCiPACT™ GMP/GDP	
POLYSORBATES				P. 18
POLYSORBATE 20	Hedjuvan-PS20	Ph. Eur., USP-NF, ChP	EXCiPACT™ GMP	
POLYSORBATE 60	Hedjuvan-PS60	Ph. Eur.	EXCiPACT™ GMP	
POLYSORBATE 80	Hedjuvan-PS80	Ph. Eur., USP-NF, ChP, JP	EXCiPACT™ GMP	
SORBITAN ESTERS				P. 20
SORBITAN MONOLAUROATE	Hedjuvan-SE20	Ph. Eur., USP-NF	EXCiPACT™ GMP	
SORBITAN MONOSTEARATE	Hedjuvan-SE60	Ph. Eur., USP-NF	EXCiPACT™ GMP	
SORBITAN MONOOLEATE	Hedjuvan-SE80	Ph. Eur., USP-NF	EXCiPACT™ GMP	
TRIA CETIN				P. 21
TRIA CETIN	ENHEX GTX99.9 PH	Ph. Eur., *	EXCiPACT™ GMP/GDP	

*Implementation of additional monographs in process.

**Current BP monograph relies on the corresponding Ph. Eur. monograph.



Glycerin

In the field of pharmaceutical formulation, the choice of excipients is crucial to ensure product efficacy, stability, and safety. Our high-quality ENHEX G glycerin (glycerol) stands out as a superior excipient, renowned for its exceptional purity and versatile properties. KLK OLEO's long expertise in glycerin manufacturing has shaped today's high quality products. As a colourless, odourless, and sweet-tasting liquid, it serves as an indispensable humectant and stabiliser in a wide range of pharmaceutical applications. Its excellent water solubility and natural moisture-retaining capabilities help maintain the integrity and effectiveness of medicines, creams, and lotions. Rigorously tested and compliant with industry standards and manufactured according to EXCiPACT™ GMP/GDP certified processes, our glycerin guarantees safety, consistency, and optimal performance, making it the ideal choice for pharmaceutical manufacturers committed to excellence.

There are different types available:

- **ENHEX G 99.8 PH:** Concentrated glycerin with min. 99.0%
- **ENHEX G 86 PH:** Diluted glycerin with min. 85% glycerin
- **ENHEX G 86 XPS:** Diluted glycerin with min. 85% glycerin **eXtra Pure** and **Stable**, our alternative to synthetic glycerin

Confirmatory testing of potential EG and DEG presence based on a representative number of batches resulted in values below 10 ppm.



	ENHEX G 99.8 PH	ENHEX G 86 PH	ENHEX G 86 XPS
Definition according to Ph. Eur. monograph 0496/0497	Glycerol	Glycerol (85 per cent)	Glycerol (85 per cent)
Glycerol content Ph. Eur.	98.0-101.0%	83.5-88.5%	83.5-88.5%
Glycerol content KLK internal specification	99.0-101.0%	85.0-88.0%	85.0-88.0%
Grade	Excipient	Excipient	Excipient
Production standard	EXCiPACT™ GMP/GDP	EXCiPACT™ GMP/GDP	EXCiPACT™ GMP/GDP
CAS No.	56-81-5	56-81-5	56-81-5
Appearance at 20°C			
Tested according to Ph. Eur. monograph	yes	yes	yes
Tested according to USP monograph	yes	n.a.	n.a.
Tested according to ChP monograph	compliant	n.a.	n.a.
Tested according to JP monograph	compliant	-	compliant
CEP	yes	-	-
NMPA registration (cDMF)	yes	n.a.	n.a.
Residual solvents according to guideline ICH Q3C	meets requirements	meets requirements	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements for parenteral applications	meets requirements for parenteral applications	meets requirements for parenteral applications
Information on EG/DEG available	yes	yes	yes
Microbiology testing (TAMC/TYMC/bacterial endotoxins)	yes, periodically	yes, periodically	yes, periodically
Sustainability Notice	vegetable-derived, RSPO MB option	vegetable-derived, RSPO MB option	vegetable-derived, RSPO MB option
Packaging	250 kg drums 1200 kg IBC bulk	250 kg drums bulk	2250 kg drums 1200 kg IBC bulk
Production site	Düsseldorf Germany	Düsseldorf Germany	Düsseldorf Germany

Liquids

Typical functions and dosage forms:

- Humectant in ointments, supports healing process
- Plasticiser in capsules to obtain soft structure
- Lubricant and sweetener in lozenges and cough syrups
- Antioxidant & preservative in inhalation aerosols
- Solvent and thickening agent in cough syrups
- Laxative in suppositories due to its hygroscopic property
- Used in injections as carrier

Our solution for critical pharmaceutical applications ENHEX G 86 XPS

With more than 100 years of experience in manufacturing glycerin in Germany, our team developed and introduced a new excipient in 2023, called ENHEX G 86 XPS, which represents a highly pure and stable pharma grade glycerin with a concentration between 85.0% and 88.0% to meet market needs of a sustainable solution as an alternative to synthetic glycerin:

- Low levels of aldehydes and ketones
- High stability
- Vegetable origin

eXtra Pure and Stable, our alternative to synthetic glycerin

ENHEX G 86 XPS is also available in drums with nitrogen inertisation

Please contact us for more details



Macrogols / Polyethylene Glycols

Macrogols / Polyethylene Glycols are the Swiss army knife of excipients, used for a multitude of functions and applications such as solubility enhancement, consistency adjustment, lubricant and binder. Known as macrogols in the European and Chinese Pharmacopoeias and as polyethylene glycols in the United States Pharmacopoeia, we simplify by referring to them as “PEGs”.

PEGs are synthesised by polymerisation of ethylene oxide, leading to a defined average polymer length and respective molecular weight, the latter indicated by a number in the excipient`s name. Low molecular weight PEGs up to PEG 1000 are liquids and commonly used as solubilising agent`s in liquid or semi-solid formulations. High molecular weight PEGs, like PEG 1500 and above, are pastes or solids and frequently applied as lubricants and binders for tableting, or as carrier and plasticiser for hot melt extrusion.

Solid PEGs are commonly processed in pastille or powder form, each with certain benefits for specific processing environments. Both physical forms are available for our solid PEG grades.

Additional microbiological burden testing (TAMC/TYMC/bacterial endotoxins) as well as lower Dioxane limits available for selected products.



As certain processes might require elevated temperatures, our products are optionally also available with a suitable antioxidant to prevent potential degradation.



Kolb Name	Hedjuvan-MG300	Hedjuvan-MG400	Hedjuvan-MG600	Hedjuvan-MG1000	Hedjuvan-MG1500	Hedjuvan-MG3350	Hedjuvan-MG4000
Ph. Eur. Name	Macrogol 300	Macrogol 400	Macrogol 600	Macrogol 1000	Macrogol 1500	Macrogol 3350	Macrogol 4000
USP Name	Polyethylene Glycol 300	Polyethylene Glycol 400	Polyethylene Glycol 600	Polyethylene Glycol 1000	Polyethylene Glycol 1500	Polyethylene Glycol 3350	Polyethylene Glycol 4000
Grade	Excipient	Excipient	Excipient	Excipient	Excipient	Excipient	Excipient
Production Standard	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP
CAS No.	25322-68-3	25322-68-3	25322-68-3	25322-68-3	25322-68-3	25322-68-3	25322-68-3
Appearance at 20 °C							
Tested according to Ph. Eur.	yes	yes	yes	yes	yes	yes	yes
Tested according to USP	yes	yes	yes	yes	yes	no	yes
Residual solvents according to guideline ICH Q3C	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements	meets requirements
Information on DEG/EG available?	on CoA	on CoA	on CoA	on CoA	on CoA	on CoA	on CoA
Microbiological testing (TAMC/TYMC/bacterial endotoxins)	no	yes	no	no	no	yes	yes
Sustainability notice	Circular Grade available	Circular Grade available	Circular Grade available	Circular Grade available	Circular Grade available	Circular Grade available	Circular Grade available
Packaging	bottle on request 25 kg can 200 kg drum 1000 kg IBC	bottle on request 25 kg can 200 kg drum 1000 kg IBC	bottle on request 25 kg can 200 kg drum 1000 kg IBC	bottle on request 25 kg can 200 kg drum IBC on request	20 kg bag big bag on request	25 kg bag big bag on request	25 kg IBC 500 kg (powder)
Production Site	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland

Liquids Solid

Typical functions, dosage forms and applications

Oral

Low molecular weight PEGs are excellent solvents, making them ideal for use in oral dosage such as syrups, drops, sprays,prays, fillings for soft shell capsules, and many more. High molecular weight PEGs are used in oral applications as well, but serve different functions. They are primarily used for tableting purposes where they act as binders and lubricants. Due to their low melting point as well as multiple polymer length options to choose from, they are very suitable for hot melt extrusion, e.g. acting as carriers and plasticisers.

Topical

PEGs are ideal for use as bases for creams and ointments, as they not only increase solubility and dissolution, but can also be utilised to adjust consistency of these dosages. Low and high molecular weight PEGs can easily be blended within the same preparation, providing the possibility to specifically adjust consistency and other characteristics of the semi-solid. Preparations combining three or more PEG grades exist, providing many and flexible options for semi-solid formulation.

Ophthalmic

Eye drops, solutions and suspensions for ophthalmic use are commonly formulated with PEGs, where they typically serve as lubricant. Similar to topical applications, different PEG grades can be combined to obtain suitable gels and other semi-solid dosages for ophthalmic use.

Parenteral

As PEGs have a very good safety profile, several grades are used in marketed injectables. Common applications are e.g. vaccines, prefilled syringes and lyophilisates for re-suspension, where they typically serve as solvents and solubilisers.

Anal / Vaginal

Due to their very suitable characteristics as lubricants and binders, as well as their ability to enhance dissolution, PEGs are also frequently used as bases for anal and vaginal suppositories.

Solid PEG grades are available as powder and as pastilles.



Macrogol Lauryl Ether (Polidocanol)

Macrogol Lauryl Ether serves as an emulsifier and solubiliser in pharmaceutical products, primarily in creams and lotions. Various types of Macrogol Lauryl Ethers are described in monographs, with the most common being Macrogol Lauryl Ether with an ethoxylation grade of 9 mol. Polidocanol is mainly utilised in ointments for itching relief and as a local anesthetic.

Overview of Possible Functions and Dosage Forms

- Emulsifying agent in oral liquids
- Wetting and/or solubilising agents in oral liquids
- Ingredient in diagnostic reagents
- others

Hedjuvan-PD9	
Ph. Eur. Name	Macrogol Laurylether (9 EO)
USP Name	Polyoxyl Lauryl Ether (9 EO)
Grade	Excipient
Production Standard	GMP EXCiPACT™ IPEC GMP
CAS No.	9002-92-0
Appearance at 20 °C	
Tested according to Ph. Eur.	yes
Tested according to USP monograph	no
Residual solvents according to guideline ICH Q3C	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements
Information on DEG/EG available?	yes
Sustainability notice	Circular Grade available
Packaging	bottle on request 25 kg can 180 kg drum IBC on request
Production Site	Hedingen, Switzerland

 Liquids

Medium-Chain Triglycerides (MCT)

Derived from renewable, carefully sourced coconut or palm kernel oils, MCTs are rapidly metabolised, providing an efficient energy source and facilitating the delivery of active ingredients. Thanks to their excellent solubility and stability, MCTs are ideal for use in softgel capsules, emulsions, and lipid-based formulations and nanoparticles.


ENHEX MCT 64, our high-quality medium-chain triglyceride (MCT), is an exceptional lipophilic excipient, recognised for its purity, biocompatibility, and versatile functionality. Rigorously tested to meet the high industry standards and manufactured according to EXCiPACT™ GMP/GDP certified processes, our MCTs ensure safety, consistency, and optimal performance in pharmaceutical applications. Trust in our premium MCTs to support innovative, effective, and reliable life science solutions.


ENHEX MCT 64	
Definition acc. to Ph. Eur. monograph 0868	Triglycerides, Medium-Chain
C8:C10 ratio	~60:40 %
Grade	Excipient
Production standard	EXCiPACT™ GMP/GDP
CAS No.	65381-09-1 / 73398-61-5
Appearance at 20°C	
Tested acc. to Ph. Eur. monograph	yes
CEP available	planned
Residual solvents according to guideline ICH Q3C	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements for injections
Microbiology testing (TAMC/TYMC/bacterial endotoxins)	safety assessment
Sustainability Notice	vegetable-derived, RSPO MB option
Packaging	190 kg drums 950 kg IBC bulk
Production site	Emmerich am Rhein Germany

 Liquids

Typical functions and dosage forms:

- Solubiliser of lipophilic drugs and taste masking properties in tablets
- Seals the surface of soft gel capsules and prevents them from sticking together
- Carrier/absorption enhancer for improved bioavailability in tablets
- Emollient properties improve spreading of ointments and creams on the skin
- Used in enteral and parenteral nutrition as fast energy source

Good to know: Our MCT unit is dedicated for the production of MCT and the raw materials are 100% backwards integrated. 




3-MCPD and Glycidol are typical contaminants in vegetable fats and oils. Our validated production process of **ENHEX MCT 64** ensures **low limits of such contaminants**. 

ENHEX MCT 64 is statistically monitored and complies with limits laid down in food regulation **EU/2023/915**.

Polysorbates

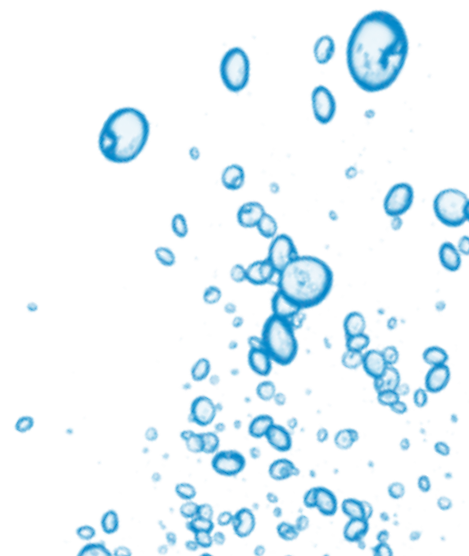
Polysorbates are among the most widely used excipients for solubilisation and emulsifying in drugs for both human and veterinary pharmaceuticals across various dosage forms.

KLK OLEO Life Science has an extensive track record in producing polysorbates. By manufacturing all intermediates and final products at our Swiss site in Hedingen, we ensure unique advantages, maintaining complete control over process, quality, storage and documentation. Consistent production parameters and reliable raw material sourcing result in outstanding batch-to-batch consistency.

Kolb Name	Hedjuvan-PS20	Hedjuvan-PS60	Hedjuvan-PS80
Ph. Eur. Name	Polysorbate 20	Polysorbate 60	Polysorbate 80
USP Name	Polysorbate 20	Polysorbate 60	Polysorbate 80
Grade	Excipient	Excipient	Excipient
Production Standard	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP
CAS No.	9005-64-5	9005-67-8	9005-65-6
Appearance at 20 °C			
Tested according to Ph. Eur.	yes	yes	yes
Tested according to USP	yes	no	yes
Tested according to ChP	yes	no	yes
Tested according to JP	no	no	yes
CEP available	yes	no	no
NMPA Registration (CDMF)	yes	no	yes
Residual solvents according to guideline ICH Q3C	meets requirements	meets requirements	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements	meets requirements	meets requirements
Information on DEG/EG available?	on CoA	yes	on CoA
Microbiological testing (TAMC/TYMC/bacterial endotoxins)	yes	no	yes
Sustainability notice	RSPO Circular grade available	RSPO Circular grade available	free of palm oil Circular grade available
Packaging	1 kg bottle 5, 10, 20 kg can 200 kg drum 950 kg IBC	1 kg bottle on request 5, 10, 20 kg can 200 kg drum on request IBC	1 kg bottle 5, 10, 20 kg can 200 kg drum 950 kg IBC
Production Site	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland

 Liquids

All polysorbates are available as Hedjuvan circular grade with drastically reduced PCF.



Added Value for Your Formulation by KLK OLEO Life Science Polysorbates

A well-established post-process step results in a product with a significantly lower impurity profile (e.g., ethylene oxide, dioxane, peroxides), meeting the stringent requirements of related monographs. This is crucial for various drug product formulations, ensuring excellent product stability over its shelf life.

Additional microbiological burden testing (TAMC/TYMC/bacterial endotoxins) for Hedjuvan-PS20 and Hedjuvan-PS80.



DEG/EG values on CoA

Currently, there are uncertainties due to potential contamination of excipients by DEG/EG. To provide our customers with assurance on this matter, the content of DEG/EG in each batch of Hedjuvan-PS20 and Hedjuvan-PS80 is specified on the certificate of analysis.

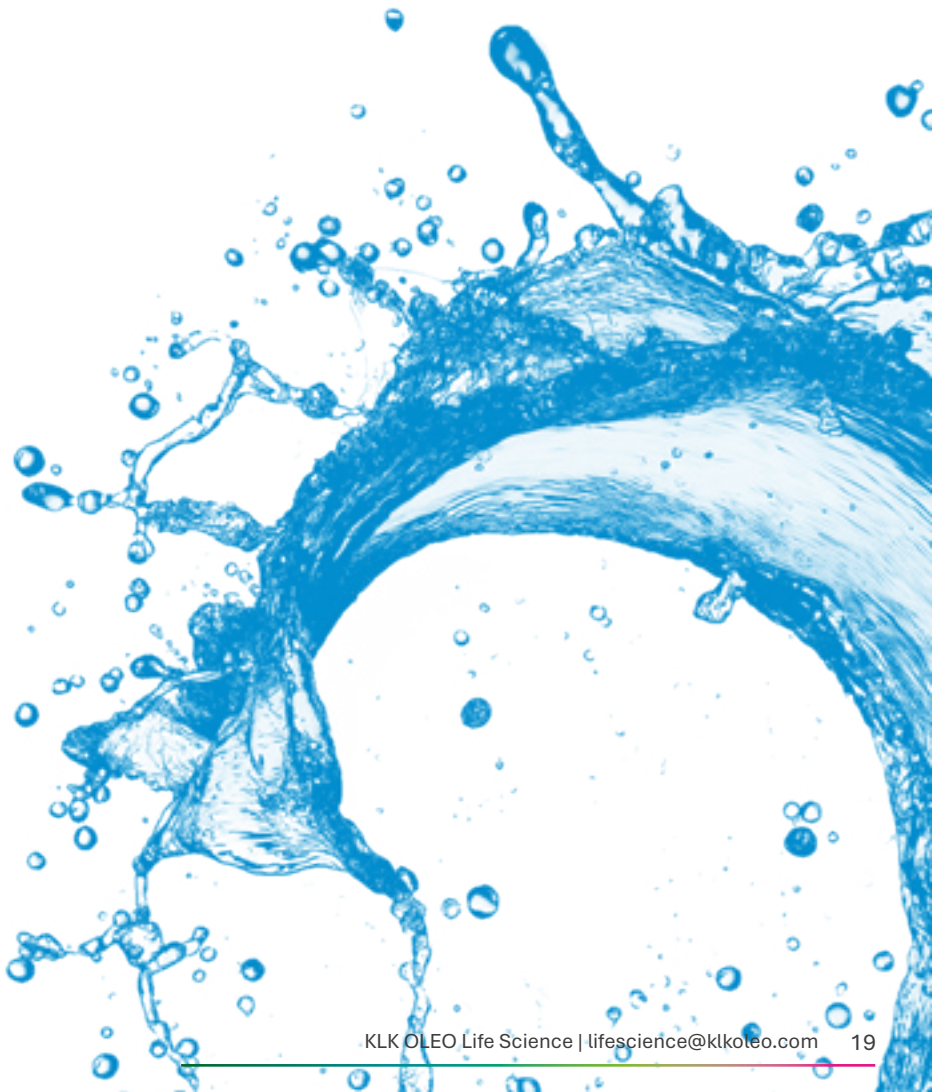
Registrations

Polysorbate 20 and Polysorbate 80 are registered with the Chinese authority (NMPA), and access to the related CDMF can be granted. Additionally, a CEP is available at the EDQM for Polysorbate 20.

We would be happy to support you during your registration process by giving access to the related documents.

Overview of Possible Functions and Dosage Forms

- Emulsifying agent in oral liquids
- Lubricant in tablets and capsules
- Glident and/or anticaking agent in tablets and capsules
- Suspending and/or viscosity increasing agent for semisolids, topicals and suppositories
- Wetting and/or solubilising agents
- Virus inactivation in blood treatment



Sorbitan Esters

All sorbitan esters are produced using bio-based raw materials. These esters are extensively used as excipients for solubilisation and emulsifying in drug products for both human and veterinary pharmaceuticals across various dosage forms.

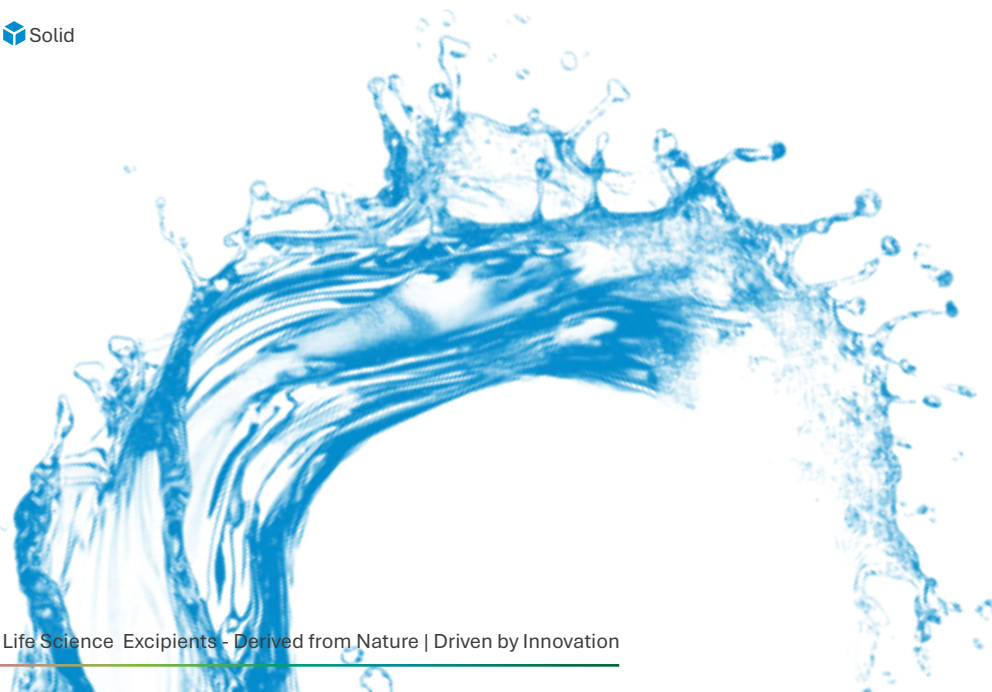
KLK OLEO Life Science has a long-standing reputation for producing sorbitan esters. Thanks to consistent production parameters and reliable raw material sourcing, KLK OLEO Life Science ensures exceptional batch-to-batch consistency and possesses extensive expertise in the characterisation of sorbitan esters.

Overview of possible functions and dosage forms

- Emulsifying agent in oral liquids
- Glident and/or anticaking agent in tablets and capsules
- Suspending and/or viscosity increasing agent for semisolids, topicals and suppositories
- Wetting and/or solubilising agents

	Hedjuvan-SE20	Hedjuvan-SE60	Hedjuvan-SE80
Ph. Eur. Name	Sorbitan Laurate	Sorbitan Stearate	Sorbitan Oleate
USP Name	Sorbitan Monolaurate	Sorbitan Monostearate	Sorbitan Monooleate
Grade	Excipient	Excipient	Excipient
Production Standard	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP	GMP EXCiPACT™ IPEC GMP
CAS No.	1338-39-2	1338-41-6	1338-43-8
Appearance at 20 °C	💧	📦	💧
Tested according to Ph. Eur.	yes	yes	yes
Tested according to USP monograph	yes	yes	yes
Residual solvents according to guideline ICH Q3C	meets requirements	meets requirements	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements	meets requirements	meets requirements
Information on DEG/EG available?	n.a.	n.a.	n.a.
Sustainability notice	RSPO fully organic-based raw material	RSPO fully organic-based raw material	Palm free fully organic-based raw material
Packaging	bottle on request 25 kg can 190 kg drum IBC on request	bottle on request 190 kg drum IBC on request 25 kg bag big bag on request	bottle on request 25 kg can 190 kg drum IBC on request
Production Site	Hedingen, Switzerland	Hedingen, Switzerland	Hedingen, Switzerland


💧 Liquids 📦 Solid



Triacetin

With its excellent solubilising and plasticising properties as well as its compatibility across a wide range of APIs and dosage forms, triacetin ensures consistent performance and formulation integrity. Manufactured according to EXCiPACT™ GMP/GDP certified processes and tested against pharmacopeial specifications, ENHEX GTX 99.9 PH offers ultra-low impurity levels and high batch-to-batch consistency.

In pharmaceutical formulations, excipients are more than just carriers they are critical to the safety, stability, and efficacy of the final product. ENHEX GTX 99.9 PH, a high-purity pharmaceutical triacetin, is an excipient designed to meet stringent quality standards.

ENHEX GTX 99.9 PH	
Definition acc. to Ph. Eur. monograph 1106	TRIACETIN
Triacetin content Ph. Eur.	97.0-100.5%
Triacetin content (GC)	≥ 99.9%
Grade	Excipient
Production standard	EXCiPACT™ GMP/GDP
CAS No.	102-76-1
Appearance at 20°C	
Tested acc. to Ph. Eur. monograph	yes
Residual solvents according to guideline ICH Q3C	meets requirements
Elemental impurities according to guideline ICH Q3D	meets requirements for parenteral applications
Microbiology testing (TAMC/TYMC/bacterial endotoxins)	yes, periodically
Sustainability Notice	vegetable raw material part is non-palm glycerin
Packaging	235 kg drums 1000 kg IBC bulk
Production site	Düsseldorf Germany

 Liquids

Typical functions and dosage forms:

- Binder in tablets to create a stable and uniform dosage form
- Plasticiser in soft gel capsules to enhance flexibility
- Solvent for active ingredients
- Solvent and emulsifier in emulsion, gels & creams
- Stabiliser in coatings
- Flavour & fragrance carrier in chewable tablets or oral formulations
- Polymer film plasticiser in transdermal patches
- Plasticiser and humectant in tablet coatings

Good to know: High purity triacetin with non-palm glycerin as the vegetable raw material part.



Typical applications and dosage forms

DOSAGE FORM	CHEMICAL NAME	Polysorbate 20	Polysorbate 60	Polysorbate 80	Sorbitan Monolaurate	Sorbitan Monostearate	Sorbitan Monooleate	PEG300	PEG400	PEG600	PEG1000	PEG1500	PEG3350	PEG4000	Lauryl Ether 9 EO	Glycerin	Medium-Chain Triglycerides	Triacetin
AEROSOL, FOAM		x	x	x	x	x			x		x					x	x	
CAPSULE (VARIOUS)		x		x	x		x		x	x			x	x	x	x	x	x
CONCENTRATE				x					x		x					x		x
CREAM		x	x	x	x	x	x	x	x		x		x	x		x	x	
DOUCHE																		
DROPS				x				x								x		
EMULSION		x	x	x	x		x		x						x	x	x	
FILM							x		x							x	x	
GEL		x		x	x		x		x		x	x			x	x	x	
GRANULES				x										x				
GUM, CHEWING			x													x		
INJECTION (various)		x		x	x			x	x	x			x	x		x	x	
LIQUID			x				x	x							x			
LOTION		x	x		x	x		x							x	x		
OINTMENT		x	x	x		x	x	x	x				x	x		x	x	
PASTE				x								x				x		
POWDER (VARIOUS)		x		x	x												x	x
SHAMPOO		x	x													x		
SOAP		x														x		
SOLUTION		x	x	x		x	x	x	x	x	x	x	x	x		x	x	
SPONGE									x							x		
SPRAY (VARIOUS)		x		x	x	x	x		x							x	x	
SUPPOSITORY		x	x	x		x	x		x		x	x	x	x	x	x		
SUSPENSION		x	x	x	x	x			x				x			x	x	x
SYRUP									x							x		
SYSTEM				x			x									x		x
TABLET (VARIOUS)		x	x	x	x	x	x		x	x	x	x		x	x	x	x	x

Data in table taken from U.S. Food and Drug Administration - Inactive Ingredients in Approved Drug Products - Database - Update July 2025, downloaded August 28th, 2025. (<https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-database-download>)

APPLICATION ROUTE	CHEMICAL NAME	Polysorbate 20	Polysorbate 60	Polysorbate 80	Sorbitan Monolaurate	Sorbitan Monostearate	Sorbitan Monooleate	PEG300	PEG400	PEG600	PEG1000	PEG1500	PEG3350	PEG4000	Lauryl Ether 9 EO	Glycerin	Medium-Chain Triglycerides	Triacetin
AURICULAR (OTIC)			x				x								x			
BUCCAL			x													x		
DENTAL												x		x		x		
INTRA-ARTICULAR				x									x	x				
INTRADERMAL																x		
INTRALESIONAL				x									x					
INTRAMUSCULAR		x		x	x		x	x					x	x		x		
INTRASYNOVIAL				x									x	x				
INTRAVENOUS		x		x			x	x	x				x	x		x	x	
DERMAL																x		
NASAL		x		x	x				x				x		x	x		
OPHTHALMIC		x		x			x	x							x	x		
ORAL		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PERIODONTAL																x		
RECTAL			x	x			x		x		x	x	x	x		x		
RESPIRATORY				x												x		
SOFT TISSUE				x									x					
SUBCUTANEOUS		x		x									x			x	x	
SUBLINGUAL				x										x			x	
TOPICAL		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
TRANSDERMAL							x				x					x	x	x
VAGINAL		x	x	x		x			x		x		x	x		x		

Abbreviations

Ph. Eur. = Pharmacopoeia Europaea

USP-NF = United States Pharmacopoeia - National Formulary

ChP = Chinese Pharmacopoeia

JP = Japanese Pharmacopoeia

JPE = Japanese Pharmaceutical Excipient

BP = British Pharmacopoeia

CAS No. = Chemical Abstracts Service number

CEP = Certificate of Suitability of Monographs of the European Pharmacopoeia

NMPA = National Medical Products Administration

CDMF = Chinese Drug Master File

EG = Ethylene glycol

EO = Ethylene oxide

DEG = Diethylene glycol

GC = Gas chromatography

ISO = International Organisation for Standardisation

ICH = International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

TAMC = Total aerobic microbial count

TYMC = Total yeast and mould count





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KLK OLEO Life Science represents the strategic cooperation between KLK EMMERICH GmbH, Kolb Distribution Ltd., and KLK Kolb Specialities B.V. to offer innovative solutions in the field of life science.

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