

Where Exceptional Quality Meets Longstanding Expertise

Hedjuvan - Swiss Made Excipients 



KLK

OLE

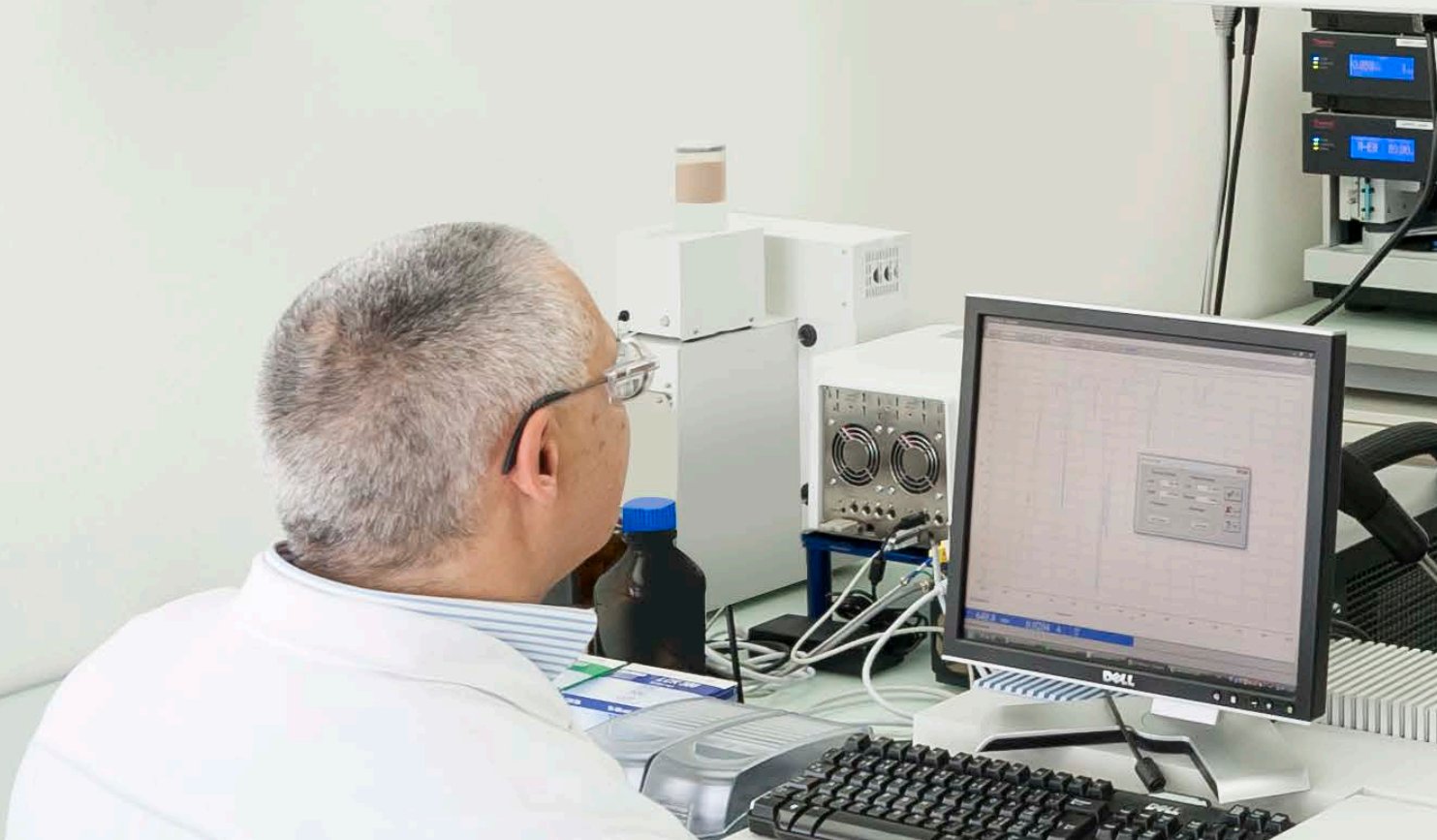
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KLK Kolb Excipients – Hedjuvan

The KLK Kolb excipients, sold under the brand Hedjuvan are all manufactured at the site in Hedingen (Switzerland) and have a wide range of applications within the human and veterinary pharmaceutical industry as well as in biopharmaceutical applications. As surfactants, they are mainly involved in surface-to-surface interaction processes such as shear protection or solubilizing and emulsifying. Thus they play a substantial role in enabling the active ingredient to unfold its full potential or to maximise the yield of a process. Therefore, they are also used in almost every dosage form such as tablets, capsules, syrups, ointments, injections and others.

Functions

Increase
Drug
Bioavailability

Virus
Deactivation
in Blood
Separation

Shear
Protection
in Biopharma
Application

Viscosity
Adjustment

Emulsifier
System

and many
more



Dosage Forms

Tablets & Capsules

Ointments

Suppositories

Syrups

Dental Gels

Solutions

Eye Drops

and many more



More than 55 Years' Experience in Alkoxylation & Esterification

KLK Kolb has more than 55 years' of experience in producing non-ionic surfactants with a proven track record of quality and reliability.

Polysorbates (ethoxylated sorbitan esters) and macrogols (polyethylene glycols) are widely used in many different applications and dosage forms. Sorbitan esters are used as excipients in the pharmaceutical industry but they are also an essential raw material for the production of polysorbates made by KLK Kolb at its Swiss site in Hedingen. This is a unique aspect contributing to KLK Kolb's exemplary proficiency in manufacturing polysorbates and sorbitan esters of high quality for decades.

In line with industry standards, we have a well-trained workforce as well as the necessary processes and documentation in place. As such, we are a reliable partner for your excipient supply chain.

In 2022, KLK Kolb received the certification of GMP EXCiPACT. Besides the excellence of KLK Kolb in manufacturing this certification is a reflection of the Kolb mindset to meet highest requirement of our customers in the pharmaceutical industry.





Certifications, Membership and Award

ISO Certifications

The different ISO certifications are the foundation of the production standard at KLK Kolb. Most of the additional certifications are based upon the ISO certifications.



GMP EXCiPACT

KLK Kolb is GMP EXCiPACT certified and produces most of the excipients in accordance to this standard.

Excipients which are not yet covered under GMP EXCiPACT are produced under ISO9001:2015 IPEC GMP.



Ecovadis

In 2022 KLK Kolb earned a platinum medal for a successful assessment by Ecovadis.

This is the highest award, given only to the top 1% participants.

KLK Kolb is proud that the effort we invest in supply chain an sustainability project is reflected in this excellence rating.



www.ecovadis.com

Free of Animal-Based Materials

To exclude any contamination with material of animal origin, the whole production site is free of animal-based raw materials and processing aids.



Kosher | Halal

All of the KLK Kolb pharmaceutical grade excipients are Kosher and Halal compliant products. Some of them are certified and for some of them statements are available.

Please contact us to learn more about the Kosher and Halal status of our products.

IPEC Europe Membership

Since 2018, KLK Kolb is an active member of IPEC-Europe and therefore we are in close exchange with other excipient producers, associations and authorities. This supports us to provide our customers also with the current and future hot issues of the pharmaceutical industry.

Sustainability - RSPO

KLK Kolb is part of Kuala Lumpur Kepong Berhad (KLK), a leading international plantation group based in Malaysia. Consequently, KLK Kolb is back-integrated for most of the fatty acids used to produce our sorbitan esters and polysorbates.

KLK was amongst the founding members of the Roundtable on Sustainable Palm Oil (RSPO) in 2004 and substantially involved in the development of a comprehensive Sustainability Policy in 2014, adopting the Principles and Criteria (P&C) of RSPO as the foundation of KLK's sustainability practices. The crust of the policy relates to the commitment towards No Deforestation, No Peat and No Exploitation (NDPE).

Therefore KLK Kolb offers all sorbitan esters and polysorbates as RSPO mass balance (MB) grade where applicable.



Roundtable on Sustainable Palm Oil (RSPO)

The RSPO, established in 2004, is a global, non-profit, multi-stakeholder initiative on sustainable palm oil that unites more than 4000 members worldwide who represent all links along the palm oil supply chain. Members of RSPO, and participants in its activities come from many different backgrounds, including growers such as KLK, processors and traders, consumer goods manufacturers and retailers of palm oil products, financial institutions, environmental and social non-governmental organisations, from many countries that produce or use palm oil.

Its objective is to promote the growth and use of sustainable oil palm products through credible global standards and multi-stakeholder governance. The RSPO has developed a set of environmental and social criteria which companies must comply with, to produce Certified Sustainable Palm Oil.

The Palm Oil Supply Chain



Overview of KLK Kolb Pharmaceutical Grade Excipients

Hedjuvan – Swiss Made Excipients

Monograph Title	Product	Tested According to	Production Standard
POLYSORBATES			
Polysorbate 20	Hedjuvan-PS20	Ph. Eur. / USP / ChP	GMP EXCiPACT
Polysorbate 60	Hedjuvan-PS60	Ph. Eur.	GMP EXCiPACT
Polysorbate 80	Hedjuvan-PS80	Ph. Eur. / USP / ChP / JP	GMP EXCiPACT
MACROGOLS			
Macrogol 300	Hedjuvan-MG300	Ph. Eur. / USP	GMP EXCiPACT
Macrogol 400	Hedjuvan-MG400	Ph. Eur. / USP	GMP EXCiPACT
Macrogol 600	Hedjuvan-MG600	Ph. Eur. / USP	GMP EXCiPACT
Macrogol 1000	Hedjuvan-MG1000	Ph. Eur. / USP	GMP EXCiPACT
Macrogol 1500	Hedjuvan-MG1500	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
Macrogol 3350	Hedjuvan-MG3350	Ph. Eur.	ISO 9001:2015 / IPEC GMP
Macrogol 4000	Hedjuvan-MG4000	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
Macrogol 6000	Hedjuvan-MG6000	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
SORBITAN ESTERS			
Sorbitan Monolaurate	Hedjuvan-SE20	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
Sorbitan Monostearate	Hedjuvan-SE60	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
Sorbitan Monooleate	Hedjuvan-SE80	Ph. Eur. / USP	ISO 9001:2015 / IPEC GMP
OTHERS			
Macrogol Laurylether	Hedjuvan-PD9	Ph. Eur.	GMP EXCiPACT

Our pharma portfolio is based on products where KLK Kolb has a longstanding experience. These products are supported by multi-compendial testing to meet international requirements. A variety of documents and pharma related support to enable approval and use of these products by our customers are available.

Overview of

KLK Emmerich GmbH Excipients

for Pharmaceuticals

Made in Germany

Monograph Title	Product	Tested According to	Production Standard
GLYCERINE			
Glycerine / Glycerol	ENHEX G 99.8 PH	Ph. Eur. / USP	GMP EXCiPACT
	EDENOR G 99.8 PH	Ph. Eur. / USP	GMP EXCiPACT
	ENHEX G 86 PH	Ph. Eur.	GMP EXCiPACT
	EDENOR G 86 PH	Ph.Eur.	GMP EXCiPACT

Monograph Title	Product	Ratio C8 / C10 (%)	Tested According to	Production Standard
MCT OILS (CAPRYLIC / CAPRIC TRIGLYCERIDE)				
Medium-Chain Triglycerides	ENHEX MCT 64	60 / 40	Ph. Eur	GMP EXCiPACT
	ENHEX MCT 73*	70 / 30	Ph. Eur	GMP EXCiPACT

* Upon request

In addition to the KLK Kolb Portfolio our sister company KLK Emmerich GmbH offers a range of various grades of glycerine and medium-chain triglycerides which are EXCiPACT (GMP/GDP) certified. For ENHEX G 99.8 PH a registration at NMPA (CDMF) is established. A registration at EDQM (CEP) is filed for ENHEX G 99.8 PH as well as ENHEX MCT 64.

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Applications of

Sorbitan Esters

All sorbitan esters are produced with bio-based raw materials. Sorbitan esters are widely used as excipients for solubilization and emulsifying in drug products for human and veterinary pharmaceuticals in various dosage forms.

KLK Kolb has a long track record for the production of sorbitan esters for various markets. Due to constant production parameter setting as well as raw material sourcing, KLK Kolb has an outstanding batch to batch consistency and the experience in characterization 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 solubilizing agents



	Hedjuvan-SE20	Hedjuvan-SE60	Hedjuvan-SE80
Monograph Name	Sorbitan Monolaurate	Sorbitan Monostearate	Sorbitan Monostearate
Grade	Excipient	Excipient	Excipient
Production Standard	ISO9001:2015 IPEC GMP	ISO9001:2015 IPEC GMP	ISO9001:2015 IPEC GMP
CAS No.	1338-39-2	1338-41-6	1338-43-8
Form	Liquid	Solid / Pastilles	Liquid
Meets the specification of the Ph. Eur. Monograph	Yes	Yes	Yes
Meets the specification of the USP Monograph	Yes	Yes	Yes
Sustainability Notice	RSPO	RSPO	RSPO
Packaging	25 kg can 200 kg drum	25 kg bag	25 kg can 200 kg drum
Production Site	Switzerland	Switzerland	Switzerland

All Hedjuvan Sorbitan Esters are made in Switzerland. The extension of the GMP-EXCiPACT-Certification to include the Sorbitan Esters is planned for 2024.

Applications of Polysorbates

Polysorbates are among of the most widely used excipients for solubilization and emulsifying in drug products for human and veterinary pharmaceuticals in various dosage forms.

KLK Kolb has a long track record for the production of polysorbates for various markets but especially for the pharmaceutical market. Since we manufacture all intermediates at our Swiss site, as well as our final products, this offers unique advantages and we have complete control over quality, storage, documentation, and audit trail. Especially the constant production parameter setting as well as raw material sourcing leads to an outstanding batch to batch consistency.

Polysorbates are mostly bio-based from renewable sources except for the ethylene oxide which is of synthetic origin. All Polysorbate are manufactured according to GMP EXCiPACT.

Added Value for your Formulation by KLK Kolb Polysorbates

A well established purifying step leads to a product with a much lower impurity profile (e.g. ethylene oxide, dioxane, peroxides, ash content,...) as a requirement by the related monographs which is important for various drug product formulations related to the stability of the final product. This is reflected in a very good product stability over its shelf life.

Additional Microbiological Testing

In addition to the related monographs, for selected products the microbiological load is determined for every batch before it is released. This ensures the highest product quality and supports you in risk-based product approval for your application.

Registrations

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

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 solubilizing agents
- ✓ Virus inactivation in blood treatment



	Hedjuvan-PS20	Hedjuvan-PS60	Hedjuvan-PS80
Monograph Name	Polysorbate 20	Polysorbate 60	Polysorbate 80
Grade	Excipient	Excipient	Excipient
Production Standard	GMP EXCiPACT	GMP EXCiPACT	GMP EXCiPACT
CAS No.	9005-64-5	9005-67-8	9005-65-6
Form	Liquid	Liquid	Liquid
Meets the Specifications of the Ph. Eur. Monograph	Yes	Yes	Yes
Meets the Specifications of the USP Monograph	Yes	-	Yes
Meets the Specifications of the ChP Monograph	Yes	-	Yes
Meets the Specifications of the JP Monograph	n.a.	n.a	Yes
TAMC	≤ 100 CFU/g	-	≤ 100 CFU/g
TYMC	≤ 10 CFU/g	-	≤ 10 CFU/g
Bacterial Endotoxins	≤ 12 IU/g	-	≤ 12 IU/g
CEP Available	In preparation	In preparation	In preparation
NMPA Registration (CDMF)	FA20230000060	In preparation	F20190000592
Sustainability Notice	RSPO	RSPO	Palm oil free
Packaging	1 kg bottle on request 5 kg can on request 25 kg can 200 kg drum 950 kg IBC	25 kg can 200 kg drum	1 kg bottle on request 5 kg can on request 25 kg can 200 kg drum 950 kg IBC
Production Site	Switzerland	Switzerland	Switzerland



All Hedjuvan Polysorbates are produced in Switzerland according to GMP-EXCiPACT.

Applications of

Macrogols & Polyethylene Glycols

Macrogols and Polyethylene Glycols are the Swiss pocket knife of the excipients. They are used for many different applications/functions and they are part of a wide range of pharmaceutical formulations. While this product group is called macrogols in the European - and Chinese Pharmacopoeia, they are referred to polyethylene glycols in the United States Pharmacopoeias. For the sake of simplicity, we call them just macrogols.

To meet the international requirements of the market, all Macrogols are tested according to the European Pharmacopoeia as well as according to the United States Pharmacopoeia (except of Macrogol 3350). For selected grades also microbiological testing such as TAMC/TAMC and bacterial endotoxins is carried out on each batch.

	Hedjuvan-MG300	Hedjuvan-MG400	Hedjuvan-MG600
Chemical Description	Polyethylene Glycol	Polyethylene Glycol	Polyethylene Glycol
Monograph Name Ph. Eur.	Macrogol 300	Macrogol 400	Macrogol 600
Monograph Name USP	Polyethylene Glycol 300	Polyethylene Glycol 400	Polyethylene Glycol 600
INCI Nomenclature	PEG-6	PEG-8	PEG-12
Grade	Excipient	Excipient	Excipient
CAS No.	25322-68-3	25322-68-3	25322-68-3
Production Standard	GEMP EXCiPACT	GEMP EXCiPACT	GEMP EXCiPACT
Appearance	Liquid	Liquid	Liquid
Average Molecular Weight [g/mol]	300*	400*	600*
Meets the Specification of the Ph. Eur. Monograph	Yes	Yes	Yes
Meets the Specification of the USP Monograph	Yes	Yes	Yes
Ph. Eur. Formaldehyde [ppm]	≤ 15	≤ 15	≤ 15
Ph. Eur. TAMC [CFU/g]	-	≤ 100	-
Ph. Eur. TYMC [CFU/g]	-	≤ 10	-
Ph. Eur. Bacterial Endotoxins [IU/g]	-	≤ 12	-
Packaging	25kg can 200kg drum	25kg can 200kg drum	25kg can 200kg drum
Production Site	Switzerland	Switzerland	Switzerland

* +/- 5% ** +/- 10%



All Hedjuvan Macrogols are produced in Switzerland. The liquid Macrogols are produced according to GMP EXCiPACT. The extension of this certification for the solid Macrogols is planned for 2024.

Macrogols as Excipient in

Oral Dosage Forms

Especially low molecular weight macrogols are very good solvents and therefore often used in oral dosage forms such as syrups or drops.

For tablets, macrogols perform a different function for they are used as binders and lubricants during the tableting process. Furthermore certain types of macrogols are used as coating and/or anticaking agent. The amount used depends on the related function of the excipient.

Topical Applications

Macrogols are used as ointment base for creams and also act as a solvent in such formulations.

Ophthalmic Applications

Macrogol is a common lubricant for eye drops.

Injectables

In many liquids for injections, such as vaccines, macrogols are used as solvents and solubilizers.

Suppositories

One of the main applications for macrogols as excipients besides binders and lubricants in tablet processing are suppositories where the macrogol is used as base material for the suppository.

Hedjuvan-MG1000	Hedjuvan-MG1500	Hedjuvan-MG3350	Hedjuvan-MG4000	Hedjuvan-MG6000
Polyethylene Glycol	Polyethylene Glycol	Polyethylene Glycol	Polyethylene Glycol	Polyethylene Glycol
Macrogol 1000	Macrogol 1500	Macrogol 3350	Macrogol 4000	Macrogol 6000
Polyethylene Glycol 1000	Polyethylene Glycol 1500	Polyethylene Glycol 3350	Polyethylene Glycol 4000	Polyethylene Glycol 6000
PEG-20	PEG-32	PEG-75	PEG-90	PEG-150
Excipient	Excipient	Excipient	Excipient	Excipient
25322-68-3	25322-68-3	25322-68-3	25322-68-3	25322-68-3
GEMP EXCiPACT	ISO 9001:2015 / IPEC GMP	ISO 9001:2015 / IPEC GMP	ISO 9001:2015 / IPEC GMP	ISO 9001:2015 / IPEC GMP
Solid	Solid / pastilles	Solid / pastilles	Solid / pastilles	Solid / pastilles
1000**	1500**	3350**	4000**	6000**
Yes	Yes	Yes	Yes	Yes
Yes	Yes	No	Yes	Yes
≤ 15	≤ 15	≤ 15	≤ 15	≤ 15
-	-	≤ 100	≤ 100	-
-	-	≤ 10	≤ 10	-
-	-	≤ 12	≤ 12	-
25kg can 200kg drum	25kg bag	25kg bag	25kg bag	25kg bag
Switzerland	Switzerland	Switzerland	Switzerland	Switzerland

Applications of Poloxamer 188

Poloxamers are synthetic block copolymers of ethylene oxide and propylene oxide, where polyoxypropylene is the center core, flanked on the left and right by polyoxyethylene.

Based on longstanding experience on alkoxylation, KLK Kolb has an outstanding batch to batch consistency, which is especially important for biopharma manufacturers. Within the specification of Poloxamer 188 the product capabilities can significantly vary, depending on the application. Therefore KLK Kolb offers various grades of Poloxamer 188 and gives you the opportunity to choose the one which perfectly suits your application.

For the Poloxamer 188 KLK Kolb entered into a partnership for the development and distribution. With this partnership we unite the excellence in manufacturing of KLK Kolb with a deep understanding of the market and the application of Poloxamer 188 which leads to a unique advantage for our customers. If you are interested in Poloxamer 188 please contact us and we will establish contact with our partner to find the perfect grade for your application.



Average molecular mass: 7680 – 9510 Da

Pharmacopoeia	Parameter	Specification
Ph. Eur.	Appearance	White to almost white solid
Ph. Eur.	Form	Granules
Ph. Eur. / USP	Average molecular mass	7680 – 9510 g/mol
Ph. Eur. / USP	Content of oxyethylene	79.9 – 83.7 %
USP	Unsaturation	≤ 0.034 mEq/g
Ph. Eur.	pH (10g/100ml)	5.0 – 7.5
USP	pH (25g/100ml)	5.0 – 7.5
Ph. Eur. / USP	Free ethylene oxide	≤ 1ppm
Ph. Eur. / USP	Free propylene oxide	≤ 5ppm
Ph. Eur. / USP	Free dioxane	≤ 10ppm
Ph. Eur.	Water content	≤ 1.0 %
Ph. Eur.	Total ash	≤ 0.4 %
Ph. Eur.	TAMC	≤ 100 KBE/g
Ph. Eur.	TYMC	≤ 10 KBE/g
Ph. Eur.	Endotoxins	Conform



Applications of Macrogol Lauryl Ether (Polidocanol)

Macrogol Lauryl Ether is an emulsifier and solubilizer in pharmaceutical products which are mainly creams or lotions. In the monographs, various types of Macrogol Lauryl Ethers are described. The most common type of this family is the Macrogol Lauryl Ether with an ethoxylation grade of 9 mol and is also known as Polidocanol or as Lauromacrogol 400, when it is used as an active ingredient. Polidocanol is mainly used in ointments against itching and as a compound for local anaesthetic.

Besides the application as excipient and active drug substance, Polidocanol is also used as ingredient in diagnostic reagents. KLK Kolb currently doesn't offer the API grade.

	Hedjuvan-PD9
Chemical name	Polyethylene glycol monolauryl ether (9EO)
Ph.Eur.	Macrogol Lauryl Ether
Chemical formula	$C_{30}H_{62}O_{10}$
INCI	Laureth-9
CAS Nr.	9002-92-0
Molecular weight [g/mol]	Approx. 583
Density [g/cm ³]	Approx. 0.98 (at 25 °C)
Appereance / Form	White pasty mass
Melting point [°C]	Approx. 20 °C
Pharmacopoeial compliance	Current Ph.Eur. at time of production



Hedjuvan-PD9 is manufactured in Switzerland according to GMP-EXCiPACT.

Overview of Possible Functions and Dosage Forms

- ✓ Emulsifying agent in oral liquids
- ✓ Wetting and/or solubilizing agents in oral liquids
- ✓ Others






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