# **Technical Information**

# Kollisolv<sup>®</sup> PEG 400

Polyethylene Glycol USP/NF, FCC, Macrogols Ph. Eur., Macrogol 400 JP

Liquid polyethylene glycols for the pharmaceutical industry.

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 $\ensuremath{\mathbb{R}}$  = Registered trademark of BASF in many countries.

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# 1. Technical properties

# Description

Kollisolv® PEG 400 is colorless, almost odorless and tasteless liquid at room temperature. The product is manufactured by alkali-catalysed polymerization of ethylene oxide with subsequent neutralization of the catalyst.

# Structural formula

$$HO = CH_2 - CH_2 - O = n$$

n represents the average number of oxyethylene groups

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The number in the name of the product indicates its average molecular weight.

#### **CAS-number**

25322-68-3

#### Hygroscopicity

At room temperature and 80% r. h. approx. 50% of increase of weight was noted over a period of 42 days.

#### Molecular weight

The average molecular weight is 400 g/mol.

# Solubility

Kollisolv<sup>®</sup> PEG 400 is readily soluble in water, ethanol, acetone, glycols and chloroform and insoluble in ether, paraffin, oils and fats.

#### Viscosity

Temperature: 20 °C – 80 °C GP: 500 1/s



Figure 1: Dynamic viscosity of Kollisolv® PEG 400

#### Approximate density

At 20 °C density is approx. 1.13 g/cm<sup>3</sup>

# 2. Handling

3. Example application

Please refer to the individual Material Safety Data sheet (MSDS) for instructions on safe and proper handling and disposal.

#### Softgels

Kollisolv<sup>®</sup> PEG 400 and other low molecular weight PEGs are very commonly used hydrophilic Softgel fills. It is critical for this application that the aldehyde level in the PEGs is very low, to prevent to crosslinking of the Gelatin. Nevertheless, these are a potent, low viscosity fill that can be utilized in conjunction with a multitude of surfactants and polymers depending on the application.

For example, when intending to increase the solubilization capacity of Kollisolv® PEG 400 in a Softgel fill, it can be used in combination with other BASF solubilizers such as Kolliphor® RH 40, Kolliphor® EL, Kolliphor® HS 15 to enhance the ability to dissolve challenging APIs.

Kollisolv<sup>®</sup> PEG 400 LA is manufactured in Geismar, LA, and is stored in steel drums purged with Nitrogen. This packaging configuration and storage condition ensures that oxidation, and the growth of aldehyde levels is kept to an absolute minimum, as required by the Softgel application. Stability data is available upon request.

#### Example formulation:

95% Kollisolv® PEG 400 LA 5% Kolliphor® RH 40 95% Kollisolv® PEG 400 LA 5% Kolliphor® HS 15

Furthermore, preventing drug recrystallization is of critical importance for softgel applications. In these examples, low molecular weight polyvinylpyrrolidone (PVP) can be used as a crystallization inhibitor.

#### Example formulation:

95% Kollisolv<sup>®</sup> PEG 400 LA 5% Kollidon<sup>®</sup> 12 PF 95% Kollisolv<sup>®</sup> PEG 400 LA 5% Kollidon<sup>®</sup> 17 PF

#### **Ointment formulations**

Kollisolv® PEG ointments can be used as an alternative to traditional petrolatum-based ointment formulations. By pairing different amounts of high and low molecular weight chains, PEG ointments can be tuned for desirable rheological profiles and sensory properties.

Phase	Ingredients	Chemical name	Role	Mass (Weight%)
А	Kollisolv® PEG 400	Polyethylene Glycol 400	Solvent	50.00
	Kollisolv® PEG 3350	Polyethylene Glycol 3350	Solvent	30.00
В	Kollisolv® PG	Propylene Glycol	Solvent	20.00

Low molecular weight liquid PEG 400 can be an excellent solvent for substances that do no readily dissolve in water, leaving behind a slightly slick residue. However, stability and solubility vary dramatically with the drug used, so tests should always be performed to ensure the integrity of the API is upheld.

#### **Gel formulations – Emulgel**

At concentrations above 15%, Poloxamers 188 and 407 can be used to make gels and viscous emulsions by both emulsifying and forming phases and networks via the hydrophobic and hydrophilic interactions driven by PPO and PEO segments of the polymer, respectively.

Phase	Ingredients	Chemical name	Role	Mass (Weight%)
А	Ethanol 200 Proof		Solvent	10
	Kollisolv® PEG 400	Polyethylene Glycol 400	Solvent	15
	Glycerol		Solvent	5
В	Kolliphor® P 407	Poloxamer 407	Gelling agent	18
С	Deionized Water		Solvent	42
D	Kollicream <sup>®</sup> 3 C	Cocoyl Caprylocaprate	Emollient	10

Kolliphor® P 407 helps emulsify the Kollicream® 3 C in this formulation, resulting in a translucent white gel with a cream-like structure visible underneath the microscope. Both Kolliphor® P 407 and Kollicream® 3 C have been shown to be very mild, in vitro and in vivo.

4. Safety data sheet	Safety data sheets are available on request and are sent with every consignment.
5. Retest date and storage conditions	Please refer to Quality & Regulatory Product Information (QRPI).
6. Specification	For current specification, please speak to your local BASF sales or technical representative.
7. Regulatory status	Please refer to Quality & Regulatory Product Information (QRPI).
8. Toxicological data	The toxicological abstracts are available on request.

# 9. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packagi	ng
30554047	Kollisolv® PEG 400	50259797	0.5 kg	Plastic bottle
		50263674	1000 kg	Composite IBC (31HA1)
		50548767	130 kg	Plastic drum
		50530207	1000 kg	Composite IBC (31HA1)
		50251480	130 kg	Plastic drum
		* BASE's commercial produc	ct number	

# **10. Publications**

https://pharmaceutical.basf.com/en.html

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