

## Technical Information

December 2011

03\_111134e-01/Page 1 of 4  
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# Kollisolv™ PEG Grades

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

**(former Tradenames Lutrol E 300 and Lutrol E 400)**

**Liquid polyethylene glycols for the pharmaceutical industry**

<b>Chemical nature</b>	<p>Polyethylene glycols (PEGs) of the general formula</p> <div style="border: 1px solid black; padding: 10px; text-align: center; margin: 10px 0;"> <math display="block">\text{HO} \left[ \text{CH}_2 - \text{CH}_2 - \text{O} \right]_n \text{H}</math> </div> <p>Where     n = 6     for Kollisolv PEG 300                  n = 8     for Kollisolv PEG 400</p> <p>The number in the name of the product indicates its average molecular weight.</p>				
<b>Trivial names</b>	Polyethylene glycol, macrogol, polyglycol, polyoxyethylene and polydiol.				
<b>Description</b>	<p>Kollisolv PEG 300 and Kollisolv PEG 400 are colourless, almost odourless and tasteless liquids at room temperature.</p> <p>The products are manufactured by alkali-catalysed polymerisation of ethylene oxide with subsequent neutralisation of the catalyst.</p>				
<b>Specifications</b>	See separate document: "Standard Specification (not for regulatory purposes)" available via BASF's WorldAccount: <a href="https://worldaccount.basf.com">https://worldaccount.basf.com</a> (registered access).				
<b>Regulatory status</b>	<p>Kollisolv PEG 300, Kollisolv PEG 400 meet current Polyethylene Glycol USP/NF, FCC IV and current Macrogols Ph. Eur. monographs.</p> <p>Kollisolv PEG 400 meets current Macrogol 400 JP monograph.</p>				
<b>Solubility</b>	<p>Kollisolv PEG 300, Kollisolv PEG 400 are</p> <ul style="list-style-type: none"> <li>– <b>readily soluble in</b> water, ethanol, acetone, glycols and chloroform,</li> <li>– <b>insoluble in</b> ether, paraffin, oils and fats.</li> </ul>				
<b>Approximate density (20 °C)</b>	<table border="0"> <tr> <td style="padding-right: 20px;">Kollisolv PEG 300</td> <td>approx. 1.13 g/cm<sup>3</sup></td> </tr> <tr> <td>Kollisolv PEG 400</td> <td>approx. 1.13 g/cm<sup>3</sup></td> </tr> </table>	Kollisolv PEG 300	approx. 1.13 g/cm <sup>3</sup>	Kollisolv PEG 400	approx. 1.13 g/cm <sup>3</sup>
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<b>Hygroscopicity</b>	<p>At room temperature and 80% r. h. the following increases in weight were noted over a period of 42 days.</p> <table border="0"> <tr> <td style="padding-right: 20px;">Kollisolv PEG 300</td> <td>approx. 55%</td> </tr> <tr> <td>Kollisolv PEG 400</td> <td>approx. 50%</td> </tr> </table>	Kollisolv PEG 300	approx. 55%	Kollisolv PEG 400	approx. 50%
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<b>Fields of application</b>	<p>The low-molecular weight liquid polyethylene glycols Kollisolv PEG 300 and Kollisolv PEG 400 are excellent solvents for a large number of substances that do not readily dissolve in water. They are therefore widely used as solvents and solubilising agents for active substances and excipients in liquid and semi-solid preparations.</p> <p>It is the ability of PEGs to form complexes with active substances that is responsible for their excellent solvent power. However, equilibrium constants for complex formation vary considerably from one substance to another, and certain drugs such as Penicillin G and Bacitracin can even become inactivated. The effect of the polyethylene glycol on the efficacy and absorption of a drug must therefore always be determined in tests. With regard to incompatible substances, please see the remarks in the European Pharmacopoeia, Vol. II/3, Monographs M1, Macrogol 300, p. 3. Polyethylene glycols can also be used to adjust the viscosity of liquid pharmaceutical preparations and ointments, to modify their absorption properties and to stabilise the preparation.</p>				

In the manufacture of soft gelatin capsules, liquid macrogols can be used as carriers for dissolved or suspended drugs.

Mixtures of solid and liquid polyethylene glycols can be used as water-soluble bases for ointments, suppositories and ovula.

Because of its good solvent power, Macrogol 400 is used to remove phenol, cresol, aniline and similar compounds from the surface of skin burnt by any of these toxic substances.

For burns from chlorophenols or chlorocresols, a mixture of 2 parts Kollisolv PEG 300 and 1 part ethanol is recommended.

## Typical formulations

### 1. Dexpanthenol gel-cream (5%)

#### 1.1. Composition

Dexpanthenol (BASF)	5 g
Paraffin, liquid	10 g
Kollisolv PEG 400	15 g
Kolliphor P 407	18 g
Water	52 g

#### 1.2. Procedure

Dissolve dexpanthenol and Kollisolv PEG 400 in water, add the liquid paraffin and heat to 60 – 70 °C with stirring. Slowly stir in Kolliphor P 407 until completely dissolved. Continue gentle stirring while the mixture is cooled to room temperature, to facilitate degassing.

#### 1.3. Properties of the gel

Soft milky gel-cream.

#### 1.4. Physical stability (3 months, 40 °C)

The viscosity and appearance of the gel-creme do not change under these conditions.

### 2. Sulfadoxin solution (2% = 20 mg/ml)

#### 2.1. Composition

I. Sulfadoxin	2.0 g
Kollisolv PEG 400	68.0 g
II. Preservative	q. s.
Water	30.0 g

#### 2.2. Preparation

Prepare Solution I at 60 °C. Heat Solution II to the same temperature and slowly mix into Solution I. Then cool the mixture.

#### 2.3. Properties of the solution

A clear colourless solution of low viscosity is obtained.

#### 2.4. Chemical stability

The solution remained clear after storage for 2 weeks at 6 °C and at 20 – 25 °C.

Further examples of formulations can be found in the compendium, "Generic Drug Formulations". It is available to order from local BASF offices in looseleaf form and on CD-ROM.

**Package sizes** Polyethylene containers of 130 kg and 230 kg, and 1000 kg bulk containers.

<b>PRD-Nos.</b>	Kollisolv PEG 300	30554046
	Kollisolv PEG 400	30554047

**Storage** Dry, in closed containers

**Stability** 24 months in closed containers

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