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# Technical Information

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## Kolliphor® ELP

Macroglycerol Ricinoleate Ph. Eur.,

Polyoxyl 35 Castor Oil USP/NF

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## 1. Technical properties

### Description

Kolliphor® ELP is a solubilizer, emulsifier and primary surfactant used in a multitude of pharmaceutical formulations, with the primary indication for sensitive APIs and parenteral use.

Kolliphor® ELP, a purified grade of Kolliphor® EL was specifically developed for sensitive active ingredients, as the higher purity was found to improve their stability.

Unlike Kolliphor® EL, Kolliphor® ELP is a white to yellowish paste or cloudy liquid. It exhibits tighter specifications with regard to water content, potassium ions and free fatty acids, in particular, ricinoleic, oleic and palmitic acids.

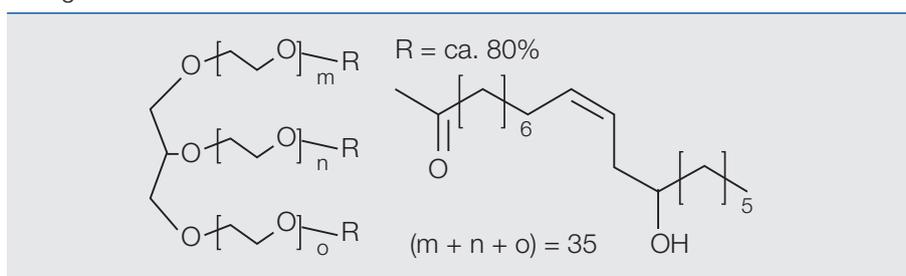
Upon heating, the last solid constituents melt at approximately 26°C to yield a clear oily liquid with a weak but characteristic odor.

### Structural formula

Kolliphor® ELP is a nonionic solubilizer and emulsifying agent obtained by reacting castor oil with ethylene oxide in a molar ratio of 1:35.

The main constituent of Kolliphor® ELP is glycerol polyethylene glycol ricinoleate, which, together with fatty esters of polyethylene glycol, this forms the hydrophobic part of the product. The hydrophilic part consists of free polyethylene glycols and ethoxylated glycerol.

A diagram of the molecular formula is listed below:



The HLB value lies between 12 and 14.

### CAS-number

61791-12-6

### Solubility

Kolliphor® ELP forms clear solutions in water. It is also soluble in many organic solvents, e.g. ethyl alcohol, n-propyl alcohol, isopropyl alcohol, ethyl acetate, chloroform, carbon tetrachloride, trichloroethylene, toluene and xylene.

In contrast to anionic emulsifying agents, Kolliphor® ELP becomes less soluble in water at higher temperatures. Thus, aqueous solutions become turbid at a certain temperature.

Kolliphor® ELP is miscible with all the other Kolliphor grades and, on heating, also with fatty acids, fatty alcohols and certain animal and vegetable oils. It is thus miscible with oleic and stearic acids, dodecyl and octa-decyl alcohols, castor oil, and a number of lipid-soluble substances.

### Critical micelle concentration

The critical micelle concentration (CMC) is 0.02% w/w @ 37 °C.

## 2. Handling

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

### Dispensing and Sterilization

It is recommended that Kolliphor® ELP be heated to between 50 and 60 °C and lightly agitated prior to use. Kolliphor® ELP exhibits complex melting behavior, and phase separation is known to occur depending on the shipping and storage conditions. This is easily overcome via melting and light mixing.

In order to ensure product stability during reheating, heat cycling was performed on Kolliphor® ELP. Commercial material was heated to 60 °C and held for 24 hours, then cooled and held at room temperature for a further 24 hours; this was repeated 20 times in total. The results of this stress test on the stability indicating parameters of Kolliphor® ELP are shown below, no significant deviation was noted.

Furthermore, as Kolliphor® ELP is often used in formulations that are subject to sterilization (e.g. parenterals), a stress test using a single autoclave cycle (121 °C, 20 mins) and sterile filtration (0.20 µm) were used to study 20% (w/w) solutions of Kolliphor® ELP; the consolidated results on stability indicating parameters are shown below.

### Kolliphor® ELP - 20% Solution

	Blank	Filter	Autoclave	Stress Test
<b>pH Value 20% (aq.)</b>	6.03	5.88	4.92	6.1
<b>Viscosity [mPas], 25 °C@1000 1/s</b>	7.44	7.31	7.06	7.05
<b>Aldehyde [mg/kg]</b>				
Formaldehyde	<1	1	4	2
Acetaldehyde	4	4	3	4
Propionald.	<1	<1	<1	<1
<b>Peroxide Value [meq/kg]</b>	5	2	2	1
<b>Hydoxyl Value [mg KOH/kg]</b>	21	18	19	28
<b>Iodine Value [g I2/100g]</b>	6.3	6.3	6.5	6.1
<b>Acid Value [mg KOH/g]</b>	0.1	0.1	0.1	<0.1

Note that autoclave sterilization may cause a reduction in pH of Kolliphor® ELP, as with other ethoxylated surfactants exposed to higher temperatures.

### 3. Example application

Kolliphor® ELP is the industry standard pharmaceutical surfactant used primarily as a solubilizer and emulsifier.

Most notably the product is used in the following types of formulations (common concentration show):

- Softgel Capsules – 600 mg per dose
- Ophthalmics up to 5 % w/w
- Oral Solutions and Suspensions 0.5 – 45%
- Topicals – 4% w/w
- Parenterals – approx. 50% w/w

Kolliphor® ELP is fully miscible in aqueous formulations.

#### Parenteral Administration

Kolliphor® ELP is a highly purified version of Kolliphor® EL, intended for sensitive applications. Below is a comparison of the two products:

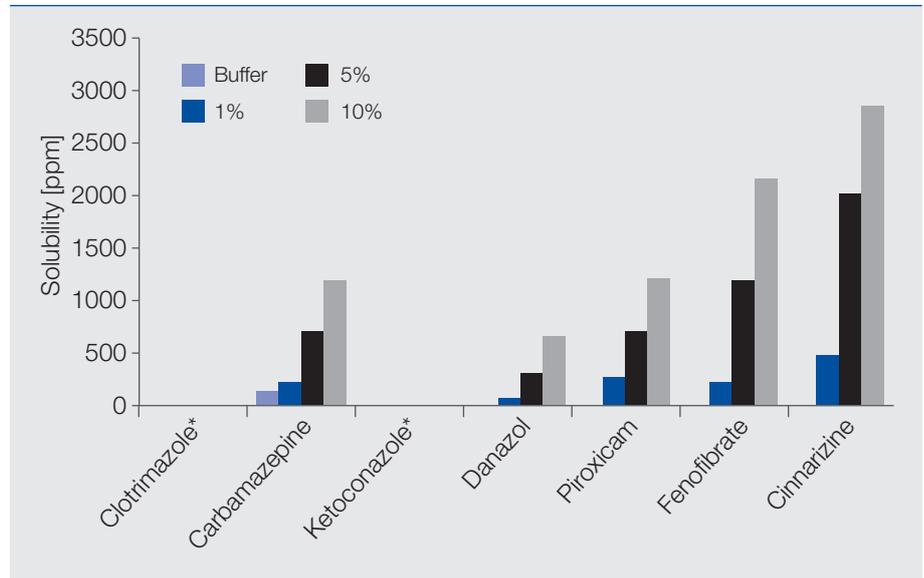
Parameter	Kolliphor® ELP	Kolliphor® EL
Appearance*	almost white paste	yellow liquid
Viscosity*, 25°C	600 – 750 mPa·s	700 – 850 mPa·s
Water	≤ 0.5%	≤ 2.8%
Potassium	≤ 15 ppm	not specified
Ricinolic acid	≤ 0.2%	not specified
Oleic acid	≤ 0.1%	not specified
Palmitinic acid	≤ 0.1%	not specified
Free fatty acids C <sub>12</sub> -C <sub>18</sub>	≤ 1.0%	not specified

\* requirements of Ph.Eur. monograph

In addition, endotoxin control and microbial testing on each released batch ensure suitability for use in parenteral applications.

## Solubilization

In addition to the high purity, Kolliphor® ELP exhibits strong solubilization potential in aqueous systems. As an example, several poorly water-soluble drugs are enhanced significantly with the addition of Kolliphor® ELP in increasing concentrations.



## 4. Important note:

One possible field of application that can be considered for Kolliphor® ELP is in parenteral dosage forms.

Thus Kolliphor® ELP is suitable for particularly demanding formulations, which prove not to achieve the desired stability when Kolliphor® EL is used.

For other injectables, we recommend Kolliphor® HS 15 as a solubilizer.

For further information, please see the Technical Data Sheets for Kolliphor® ELP and Kolliphor® HS 15.

Kolliphor® ELP promotes the penetration of a number of active substances and can exert either activating or inactivating effects on others, e. g. antibiotics. Therefore, before Kolliphor® ELP preparations are used in practice, it is advisable to subject them to thorough pharmacological tests.

Kolliphor® ELP is subjected to thorough quality controls involving comprehensive chemical and physical tests. The individual production batches are not, however, subjected to biological tests. For this reason, producers of preparations that contain Kolliphor® ELP must carry out their own tests to check the suitability of the respective material and of the final preparations.

Cattle that have been given certain vaccines or medicaments parenterally and have subsequently been injected with preparations containing Kolliphor® ELP or similar solubilizers have displayed anaphylactic reactions in isolated cases involving exceptional circumstances. Anaphylactic reactions have occasionally been observed in humans after injections containing Kolliphor® ELP. For this reason, the health authorities in the Federal Republic of Germany and the UK, for instance, have laid down that the content of polyethoxylated castor oil in injections for parenteral administration to humans must be declared, and that attention must be drawn to the possibility of side effects in the package insert. This is an aspect to which companies producing pharmaceuticals for human use must pay particular attention.

No side effects of this kind have been observed after oral administration of preparations containing Kolliphor® ELP.

## 5. Safety data sheet

Safety data sheets are available on request and are sent with every consignment.

## 6. Retest date and storage conditions

Please refer to Quality & Regulatory Product Information (QRPI).

## 7. Specification

For current specification, please speak to your local BASF sales or technical representative.

## 8. Toxicological data

The toxicological abstracts are available on request.

## 9. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30554034	Kolliphor® ELP	50539225	0.5 kg Plastic bottle
		50259800	0.5 kg Alu bottle
		50251534	60 kg Steel drums

\* BASF's commercial product number.

## 10. Publications

<http://pharmaceutical.basf.com/en.html>

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