



# Kolliphor® ELP

The highly purified solubilizer for oral, parenteral and topical applications

Did you know that Kolliphor® ELP, a purified grade of Kolliphor® EL, improves the stability of sensitive APIs?

Kolliphor® ELP can be used as non-ionic oil-in-water emulsifier and/or solubilizer. Due to its high purity, it is particularly suitable for injectable formulations.

- ✓ Widely used in approved drugs worldwide
- ✓ Highly purified and endotoxin-controlled
- ✓ Excellent compatibility with other ingredients

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## Product Benefits

- Highly purified Kolliphor® EL grade (Polyoxyl-35-castor oil)
- Endotoxin-controlled
- Excellent compatibility with other ingredients
- Especially suitable for formulations containing extremely sensitive APIs
- Compliant with Ph. Eur. and USP-NF

## Product Details

<b>Generic name</b>	Macrogolglycerol ricinoleate Polyoxyl-35-castor oil PEG-35 castor oil
<b>CAS number</b>	61791-12-6
<b>PRD number</b>	30554034
<b>Packaging size</b>	60 kg steel drum with inliner
<b>Article number</b>	50251534
<b>Manufacturing site</b>	Ludwigshafen (Germany)
<b>Physical form</b>	paste at room temperature, liquid at approx. 30 °C
<b>pH</b>	5–7
<b>HLB</b>	12–14
<b>CMC</b>	approx. 0.02%

## Regulatory Documentation

- US-DMF # 2981 (Type IV, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/Applicants Part
- Canada # 1992-046

**i** For a Letter of Authorization or a copy of the RIF, please contact your sales representative.

## Pharmacopoeia Monographs and Titles

Kolliphor® ELP meets the requirements of the current monograph of Ph. Eur. “Macrogolglycerol ricinoleate” and USP-NF “Polyoxyl-35-castor oil”.

## Preclinical Safety Data

No toxicological studies have been carried out on Kolliphor® ELP itself. Please refer to the toxicological findings for Kolliphor® EL:

- Tox Abstract (summary of the design and results of the pre-clinical studies performed)

**i** For a copy of the Tox Abstract please contact your sales representative.

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