

Technical Information

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Kolliphor™ ELP

Macroglycerol ricinoleate Ph. Eur.,
Polyoxyl-35-castor oil USP/NF

(former Tradename Cremophor ELP)

Solubiliser for the pharmaceutical industry

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

Chemical nature

Like Kolliphor EL, Kolliphor ELP is a nonionic solubiliser made by reacting castor oil with ethylene oxide in a molar ratio of 1 : 35. This is followed by a purification process.

Description

Unlike Kolliphor EL, Kolliphor ELP is a white to yellowish paste or cloudy liquid. It has to fulfill more exacting requirements with regard to water content, potassium ions and free fatty acids, particularly ricinoleic, oleic and palmitic acids.

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

The HLB value lies between 12 and 14.

The critical micelle concentration (CMC) lies at approx. 0.02%.

Regulatory status

Meets current Macrogolglycerol ricinoleate Ph. Eur. and Polyoxyl-35-castor oil USP/NF monographs.

Solubility

Kolliphor ELP forms clear solutions in water and also dissolves in a wide range of organic solvents, such as ethanol, n-propanol, isopropanol, ethyl acetate, chloroform, carbon tetrachloride, trichloroethylene, toluene and xylene.

Specification

See separate document Standard "Specification (not for regulatory purposes)" available via BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

Applications

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 solubiliser.

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

Recommendations for product handling and sampling

For proper product handling and sampling homogenization of the drum content is necessary. The new drums allow the repeated liquefaction of their content at around 60 °C. It is recommended to use electrical drum heaters, heating covers or a heating chamber.

Toxicology

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

PRD-No.

30554034

Packaging

60 kg removable-head steel drum with a Lupolen® inliner with its own lid.

Storage

Kolliphor ELP is stable for at least 24 months if stored in the unopened original containers, protected from light and at room temperature (max. 25 °C).

Prolonged storage is not recommended unless the containers are completely full.

Safety Data Sheet

A Safety Data Sheet is available for Kolliphor ELP.

Note

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