

# Soluplus®

NEW

- in Ph. Eur. “Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer” (3156)
- Chinese DMF F20210000495 (A – Activated)

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## Did you know that Soluplus is no longer a novel excipient in Europe and China?

Try Soluplus® and experience a new dimension in solubility and bioavailability enhancement.

### Soluplus® at a glance

- Polymer with an amphiphilic structure that enhances the solubility of poorly soluble APIs.
- An ideal polymer for hot melt extrusion exhibiting excellent extrudability and ensuring smooth processing.
- A matrix-forming polymer for Amorphous Solid Dispersions (ASDs)
- Enables bioavailability enhancement by improving drug dissolution and absorption.

### Product Details

Brand/Trade name	Soluplus®
Chemical name	Polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft co-polymer
Monograph name	Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer (Ph. Eur.)
PRD number	30446233
Packaging size	12.5 kg plastic drum
Article number	50477909
Quality	IPEC GMP
Manufacturing site	Ludwigshafen, Germany
Physical form	Granules

### Regulatory dossiers

- US-DMF #23504 (Type IV DMF, containing CMC information)
- Regulatory Information File “RIF” (Dossier with similar content as US-DMF #23504, excluding confidential manufacturing details for qualification purposes and registrations in countries without a DMF procedure)
- US-DMF #23626 (Type V DMF, containing safety data in line with FDA’s guidance on Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients and a single dose study in humans)
- Chinese DMF F20210000495 (A – Activated status)

### Safety data

- ✓ Safety Expert Report (equivalent to US Type V DMF #23626 containing safety data in line with FDA’s guidance on Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients and a single dose study in humans).

Available under confidentiality agreement. Please contact your sales representative.

- ✓ Safety summary (abstract of the design and results of the studies performed).

### Request the Regulatory Information File, Letters of Authorization, and additional documentation 24/7 via RegXcellence®.

Our regulatory experts can offer comprehensive support for your FDA submission of new products containing Soluplus®. For further guidance, please contact your local BASF sales representative.

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