

Soluplus®

For better solubility and bioavailability

BASF
We create chemistry

Did you know that Soluplus also solubilizes drugs processed by wet granulation?
Try Soluplus® and experience a new dimension in solubility and bioavailability enhancement.

Soluplus® at a glance

- Polymer with an amphiphilic structure enhances the solubilization properties 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
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

Request the Regulatory Information File or Letters of Authorization 24/7 via RegXcellence®.

Safety data

- ✓ Safety Expert Report (equivalent content 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).

Download 24/7 on RegXcellence®

Pharmacopoeial Monograph NEW

- Ph. Eur. Vol. 12.0: Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer" (3156)

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.

ZoomLab®
Your Virtual Formulation Assistant

RegXcellence®
Your Virtual Regulatory and Quality Assistant

MyProductWorld
Your Virtual Product Assistant



This document, or any information provided herein does not constitute a legally binding obligation of BASF and has been prepared in good faith and is believed to be accurate as of the date of issuance. Unless expressly agreed otherwise in writing in a supply contract or other written agreement between you and BASF:

(a) To the fullest extent not prohibited by the applicable laws, BASF EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY FACT OR LAW, INCLUDING ANY IMPLIED WARRANTIES, REPRESENTATIONS OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, NON-INFRINGEMENT, AND ANY REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES, ARISING FROM STATUTE, COURSE OF DEALING OR USAGE OF TRADE and BASF HEREBY EXPRESSLY EXCLUDES AND DISCLAIMS ANY LIABILITY RESULTING FROM OR IN CONNECTION WITH THIS DOCUMENT OR ANY INFORMATION PROVIDED HEREIN, including, without limitation, any liability for any direct, consequential, special, or punitive damages relating to or arising therefrom, except in cases of (i) death or personal injury to the extent caused by BASF's sole negligence, (ii) BASF's willful misconduct, fraud or fraudulent misrepresentation or (iii) any matter in respect of which it would be unlawful for BASF to exclude or restrict liability under the applicable laws;

(b) Any information provided herein can be changed at BASF's sole discretion anytime and neither this document nor the information provided herein may be relied upon to satisfy from any and all obligations you may have to undertake your own inspections and evaluations;

(c) BASF rejects any obligation to, and will not, automatically update this document and any information provided herein, unless required by applicable law; and

(d) The user is responsible for confirming that the user has retrieved the most current version of this document from BASF as appropriate

© 2025 BASF MarComm-2025-00054

Inspiring Medicines for Better Lives

in BASF Pharma Solutions
www.pharma.basf.com