

# Kollicoat® Smartseal 30 D

# Kollicoat® Smartseal 100 P

BASF's functional polymer for taste masking and moisture protection is now available as aqueous dispersion and free flowing powder

- ✓ Smart protection from unpleasant taste
- ✓ Effective sealing against moisture
- ✓ Fast release of active ingredients
- ✓ Easy and economical film coating
- ✓ Optimal coating polymer for ODT formulations, pellets and particles

## Physico-chemical Properties

Brand/Trade name	Kollicoat® Smartseal 30 D	Kollicoat® Smartseal 100 P
<b>Chemistry</b>	Methyl methacrylate and di(ethyl)aminoethyl methacrylate (7:3) copolymer	
<b>Polymer properties</b>	<ul style="list-style-type: none"> <li>■ Completely insensitive to moisture</li> <li>■ Insoluble at neutral pH</li> </ul>	<ul style="list-style-type: none"> <li>■ Readily soluble at pH &lt;5</li> <li>■ Tg ~63°C</li> </ul>
<b>Physical form</b>	30% aqueous polymer dispersion	Spray dried free flowing polymer powder of Kollicoat® Smartseal 30 D
<b>Application</b>	Aqueous film coating	<ul style="list-style-type: none"> <li>■ Re-dispersible in water after partial neutralization with e.g. succinic acid for aqueous film coating</li> <li>■ Soluble in acetone or acetone/isopropanol mixtures for organic film coating</li> </ul>

**BASF**  
We create chemistry



## Product Details

Brand/Trade name	Kollicoat® Smartseal 30 D	Kollicoat® Smartseal 100 P
PRD number	30492630	30585559
Packaging size	25 kg plastic jerricans	15 kg PE liner in cardboard box
Article number	50138477	50341064
Manufacturing site	Ludwigshafen (Germany)	

## Regulatory Documentation

- US-DMF #24389 (Type IV DMF, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/Applicants Part of a DMF
- US-DMF #24460 (Type V DMF, containing pre-clinical safety data)

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

## Preclinical Safety Data

- Tox Abstract (Summary of the design and results of the pre-clinical studies performed)
- Safety Expert Report (Detailed description of the pre-clinical safety data, as well as two clinical study reports. Available under BASF secrecy agreement)

**i** For a copy of the Tox Abstract, Safety Expert Report and our secrecy agreement please contact your sales representative.

## Regulatory Status – Overview

Country of regulatory submission	Application type	Project details	Amount of Kollicoat® Smartseal 30 D
USA	IND	Application filed. Clinical evaluation ongoing. CMC questions received from FDA in 2016. Questions answered by BASF, no further questions received.	unknown
Canada	IND	Application under preparation	unknown
Canada	IND	Filed in 2017	unknown
Europe	PIP	Pediatric Investigation Plan submission anticipated in Q3 2018.	unknown

## Pharmacopoeia Monographs and Titles

Kollicoat® Smartseal 30 D is not yet monographed in any pharmacopoeia. Upon approval the elaboration of a monograph will be initiated by BASF.

This document and any information provided herein is for your guidance only. All information is given in good faith and is based on sources believed to be reliable and accurate at the date of publication of this document. This document shall be valid until superseded by a later version.

Seller makes no warranty of any kind, either express or implied, by fact or by law, including warranties of merchantability or fitness for a particular purpose.

Get your sample today!  
[pharma-solutions@basf.com](mailto:pharma-solutions@basf.com)