

Kollicoat® Smartseal 30 D

Kollicoat® Smartseal 100 P

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

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

Physico-chemical Properties

Brand/Trade name	Kollicoat® Smartseal 30 D	Kollicoat® Smartseal 100 P
Chemistry	Methyl methacrylate and di(ethyl)aminoethyl methacrylate (7:3) copolymer	
Polymer properties	Insoluble at neutral pH Readily soluble at pH <5 Tg ~63°C	
Physical form	30% aqueous polymer dispersion	Spray dried free flowing polymer powder of Kollicoat® Smartseal 30 D
Application	Aqueous film coating	Aqueous coating (powder is re-dispersible in water after partial neutralization with e.g. succinic acid) Solvent coating (powder is soluble in acetone or acetone/isopropanol mixtures for organic film coating)

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
Sample	1 kg plastic bottle	
Article number	50138478	50635483
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 study 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 and 100 P are not yet monographed in any pharmacopoeia. Upon approval the elaboration of a monograph will be initiated by BASF.

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