
Technical Information

Kollicoat® Protect

Protective coating providing a moisture barrier and taste masking.

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® = Registered trademark of BASF in many countries.



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1. Introduction

Kollicoat® Protect is a coating based on Kollicoat® IR (polyvinyl alcohol-polyethylene glycol graft copolymer) that is very readily soluble in water.

It is used primarily as a protective coating in the manufacture of film coatings that dissolve in the gastric juices (instant-release coatings). The protection may consist in a barrier against water vapor, for taste masking formulations, or prevention of incompatibilities between ingredients.

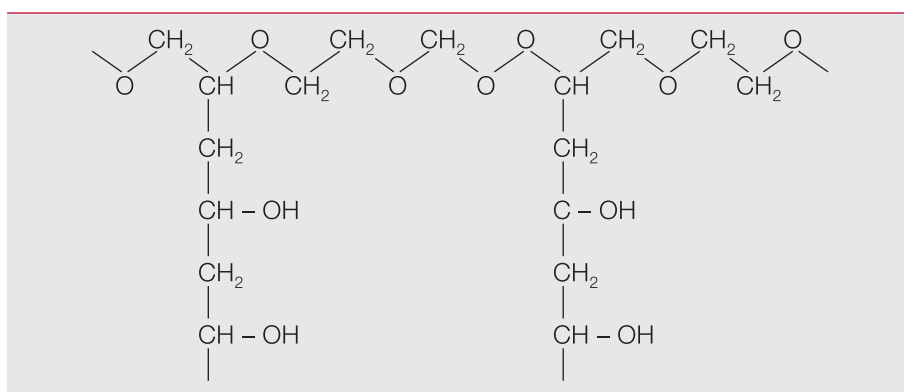
2. Technical properties

Description

Kollicoat® Protect is a white to off-white, free-flowing powder.

The recipe is based mainly on the highly flexible film former Kollicoat® IR, which has the following structure.

Structural formula



Composition

Polyvinyl alcohol-polyethylene glycol graft copolymer	55 – 65%
Polyvinyl alcohol	35 – 45%
Silicon dioxide	0.1 – 0.3%

CAS-number

96734-39-3 + 9002-89-5 + 7631-86-9

Chemical nature

Owing to the special spray-drying process for Kollicoat® Protect, the polymers are embedded in one another to such an extent that they cannot separate. The powder has good flowability and dissolves rapidly in water.

Physicochemical properties

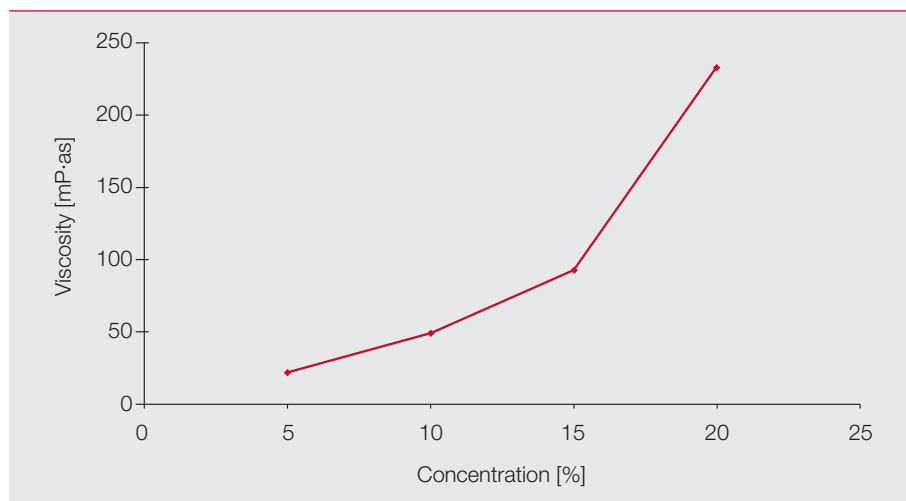
The aqueous solution has a relatively low viscosity and can be readily prepared.

Film formation

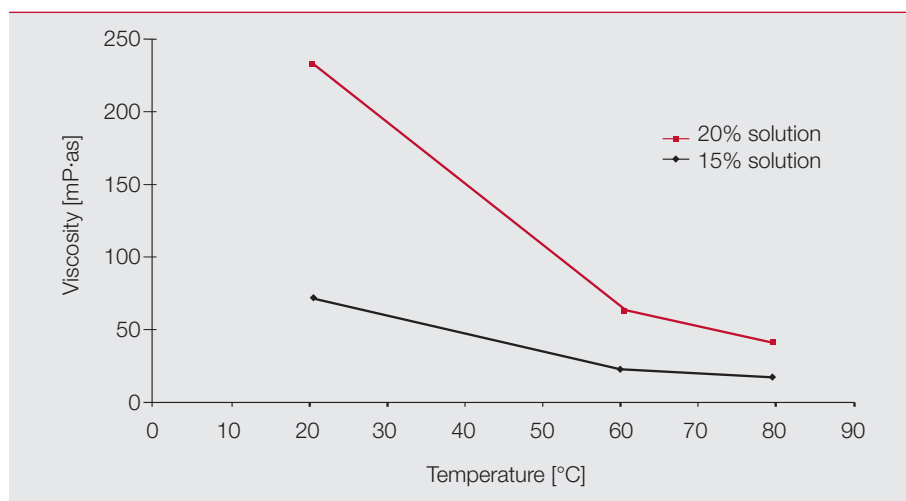
The aqueous solution is poured on to a glass plate. The water evaporates, leaving a flexible film.

Properties of aqueous solutions

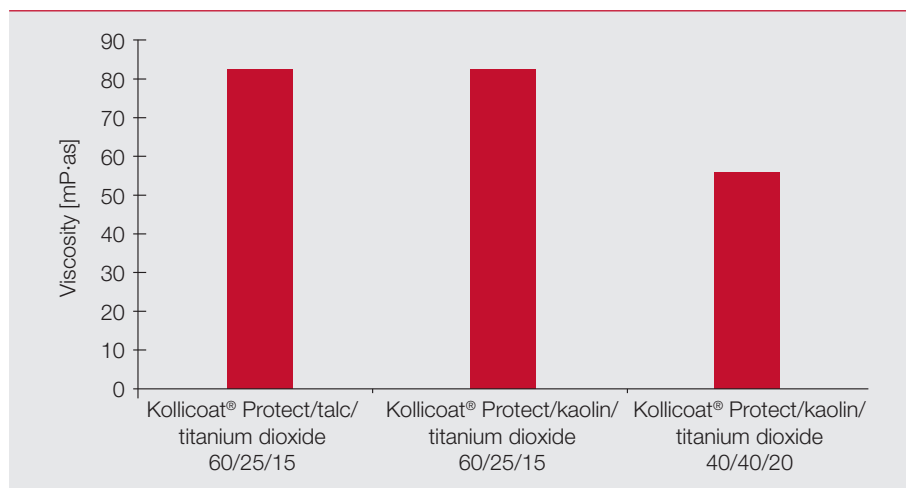
Viscosity of aqueous Kollicoat® Protect solutions as a function of polymer concentration (at 23 °C).



Viscosity of a Kollicoat® Protect solution as a function of temperature.



Viscosity of various Kollicoat® Protect spray suspensions (20% w/w, 25 °C).

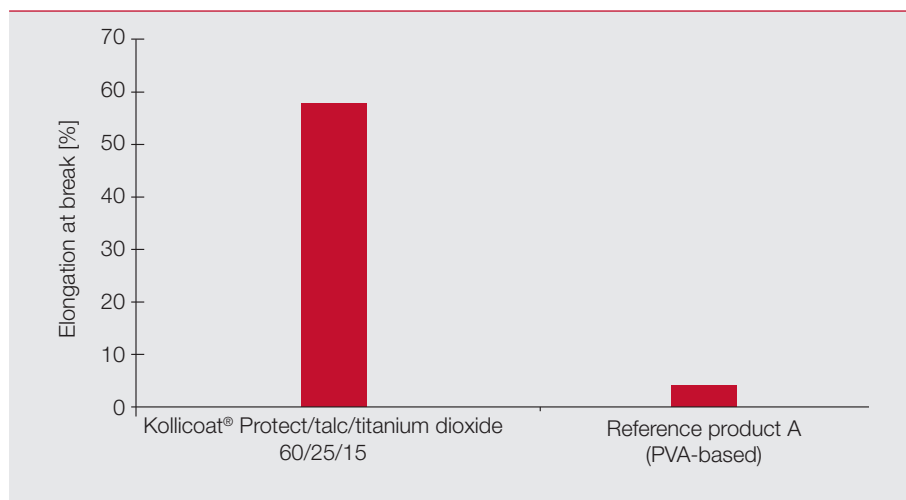


Surface tension

The surface tension of a 15% Kollicoat® Protect solution is very low (42.3 mN/m). Good wetting and spreadability are therefore achieved even on lipophilic surfaces.

Film properties

Kollicoat® Protect forms transparent, highly flexible films that dissolve very rapidly in water. Kollicoat® Protect films are not tacky and can be readily printed. Elongation at break of various moisture-barrier films (23 °C, 58% r. h.)



Adhesiveness

Kollicoat® Protect film coatings adhere extremely well to tablet surfaces of varying lipophilic character.

Coating engravings

The very low viscosity and excellent wetting and spreading properties ensure that even fine engravings are uniformly coated and no bridging occurs.

3. Example application

Applications

Kollicoat® Protect can be used in all applications where a readily soluble, flexible coating is required.

- Instant-release coating
 - Protection against moisture
 - Taste masking
 - As a subcoating
 - Improves appearance, makes tablet easier to swallow, gives distinctive coloring, protects active ingredients (prevents interaction)
- Binder
 - As a binder

Processing notes

Because of the high flexibility of Kollicoat® Protect films, it is not necessary to add a plasticizer.

Foam may form when Kollicoat® Protect is incorporated into water, to an extent that depends on the mixing conditions. Foam formation can be minimized by adding 0.1% Simethicon 30% emulsion or 0.75% Labrasol (supplied by Gattefosse).

A spray solution is conveniently prepared as follows:

- a.) Spray solution with water-soluble dye:
Stir the Kollicoat® Protect and water-soluble dye into water and dissolve. The mixer speed should be adjusted so that little or no foam is produced. After stirring for 30 min, the spray solution is ready for further processing.
- b.) Spray suspension containing pigments and/or lakes:

Film-forming solution

Stir Kollicoat® Protect into the specified quantity of water and dissolve.

Pigment suspension

Stir the insoluble components, such as talc, titanium dioxide, kaolin, lakes or color pigments, into the appropriate quantity of water and homogenize with a high-shear mixer, e.g. Ultra-Turrax.

Spray suspension

Stir the pigment suspension into the film-forming solution.

The coating can be applied on all the usual coaters, e.g. horizontal drum coaters, fluidized bed coaters, immersion sword coaters and coating pans, under the usual conditions for aqueous solutions.

The following conditions have produced good results in numerous trials:

Inlet air temperature	50 – 80 °C
Outlet air temperature	30 – 50 °C
Atomizing pressure	3 – 5 bar
Temperature of spray suspension	20 – 70 °C

Cleaning

The product can very easily be cleaned off equipment with warm or cold water.

Typical recipes

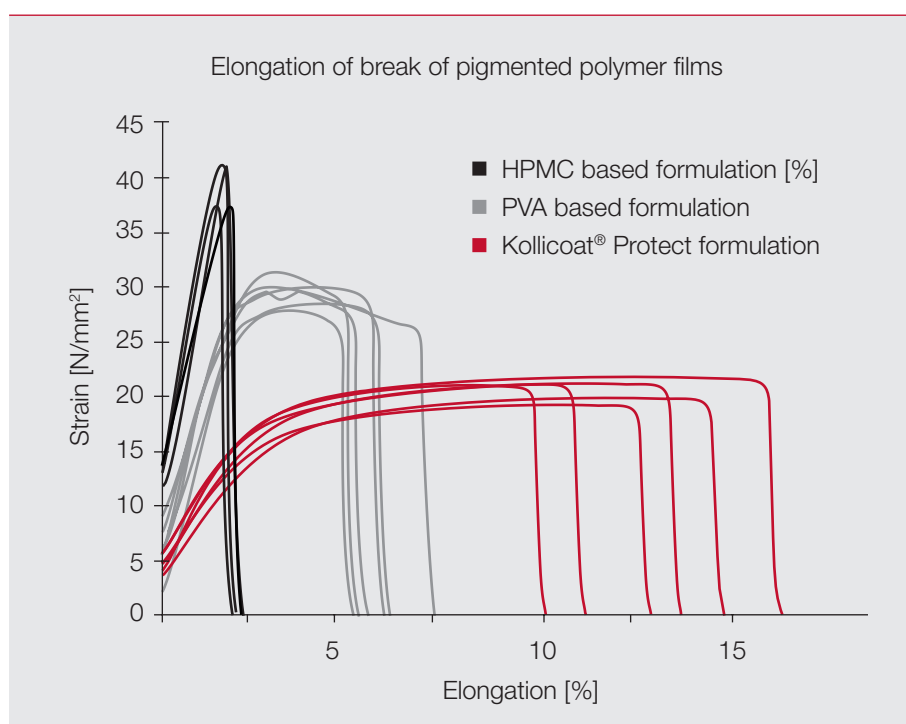
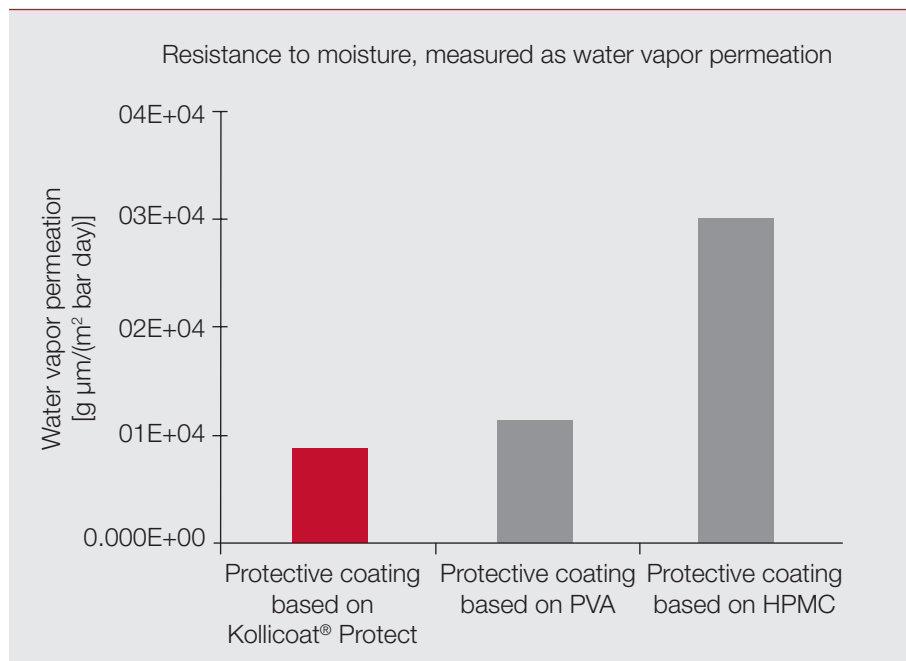
Aspirin moisture-protected film-coated tablets

Composition of tablets	100 mg acetylsalicylic acid, 148.5 mg Ludipress® LCE, 50 mg Avicel® PH 102, 1.5 mg magnesium stearate	
Composition of spray solution	The formulation is designed for 6 kg tablets (tablet weight 300 mg, diameter 9 mm)	
Spray suspension	Weight [g]	Proportion [%]
Kollicoat® Protect	125.40	12
Talc	52.25	5
Titanium dioxide	31.35	3
Water	836.00	80
	1045.00	100
Machine parameters	Coating machine	Accela-Cota drum coater (24 inch)
	Batch size	6 kg
	Inlet air temperature	60 °C
	Outlet air temperature	36 °C
	Product temperature	35 °C
	Inlet air flow	210 m³/h
	Outlet air flow	410 m³/h
	Atomizing pressure	2 bar
	Forming air pressure	1.4 bar
	Number of spray nozzles	1
	Spraying rate	30 g/min
	Spraying time	35 min
	Final drying	60 °C/4 min
	Quantity applied	5 mg/cm² solids
Tablet properties	Core	Film-coated tablet
Appearance	white	white
Hardness	67 N	79 N
Friability	0%	0%
Disintegration time	3:17 [min:s]	3:58 [min:s]

Vitamin C moisture-protected film-coated tablets

Composition of tablets	103.1 mg Vitamin C 97, 180.0 mg Ludipress, 14.4 mg Kollidon® VA 64, 5.0 mg Kollidon CL, 2.5 mg magnesium stearate	
Composition of spray suspension	The formulation is designed for 1 kg tablets (tablet weight 300 mg, diameter 8.5 mm)	
Polymer suspension	Weight [g]	Proportion [%]
Kollicoat® Protect	16.8	12.0
Water	82.6	59.0
Pigment suspension		
Talc	7.0	5.0
Titanium dioxide	4.2	3.0
Sicovit® Yellow 10	1.4	1.0
Water	28.0	20.0
	140.0	100.0
Machine parameters		
	Coating machine	Hi-Coater (Freund Industrial Co.)
	Batch size	1 kg
	Inlet air temperature	54 – 57 °C
	Outlet air temperature	34 – 35 °C
	Atomizing pressure	1.5 bar
	Number of spray nozzles	1
	Spraying rate	5.2 – 5.4 g/min
	Spraying time	29 min
	Final drying	8 min (outlet air temp. 34 – 40 °C)
	Quantity applied	3.15%
Tablet properties		
	Core	Film-coated tablet
Appearance	white	yellow
Hardness	150 N	181 N
Friability	0%	0%
Disintegration time	5:18 [min:s]	5:45 [min:s]

Comparison of polymer formulations



4. Handling & Safety

Please refer to the individual material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. Material safety data sheets are sent with every consignment. In addition they are available on BASF WorldAccount* or from your local BASF sales representative.

5. Retest date and storage conditions

Please refer to Quality & Regulatory Product Information (QRPI).

6. Specification

For current specification, please speak to your local BASF sales or technical representative.

7. Regulatory status

Please refer to Quality & Regulatory Product Information (QRPI).

8. Toxicological data

The toxicological abstract is available on request.

9. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30235579	Kollicoat® Protect	50391593	25 kg Plastic drums

* BASF's commercial product number.

10. Publications

<http://pharmaceutical.basf.com/en.html>

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