
Technical Information

Kolliphor® P 338 Geismar

Poloxamer Ph. Eur., Poloxamer USP/NF
Poloxamer for Pharmaceutical Use

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® = Registered trademark of BASF in many countries.

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1. Introduction

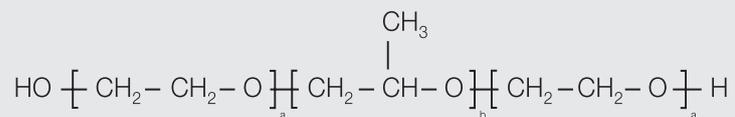
BASF's Kolliphor P grade poloxamers are white, coarse-grained powders with a waxy consistency. They contain an appropriate quantity of the antioxidant BHT.

Poloxamers are ABA-type co-polymers of poly (ethylene oxide) (PEO=A) and poly (propylene oxide) (PPO=B). The approximate relative amount of PEO and the average molecular weight of the PPO are indicated in the name of the poloxamer. For example, P338 succeeding the word Kolliphor® indicates a poloxamer with ca. 80% m/m PEO (P338; $8 \times 10 = 80\%$) and approximately average molecular weight of PPO of 3300 (P338; $33 \times 100 = 3300$).

2. Technical properties

Structural formula

Kolliphor® P 338 Geismar is a block copolymer that is a synthetic copolymer of ethylene oxide and propylene oxide represented by the following chemical structure:



Where the a and b blocks have the following values:
a = 141, b = 44

Appearance

Kolliphor® P 338 Geismar is produced as a white to almost white prill/powder.

CAS Number

9003-11-6

Molecular Weight

The average molecular weight for Kolliphor® P 338 Geismar is 12700 to 17400 g/mol. The product contains nominally 135 to 145 ethylene oxide units and 40 – 50 propylene oxide units, with a rough concentration of oxyethylene of 81.4 – 84.8 % based on the current monograph specification. An example of the molecular weight distribution for Kolliphor® P 338 Geismar is shown below in Figure 1.

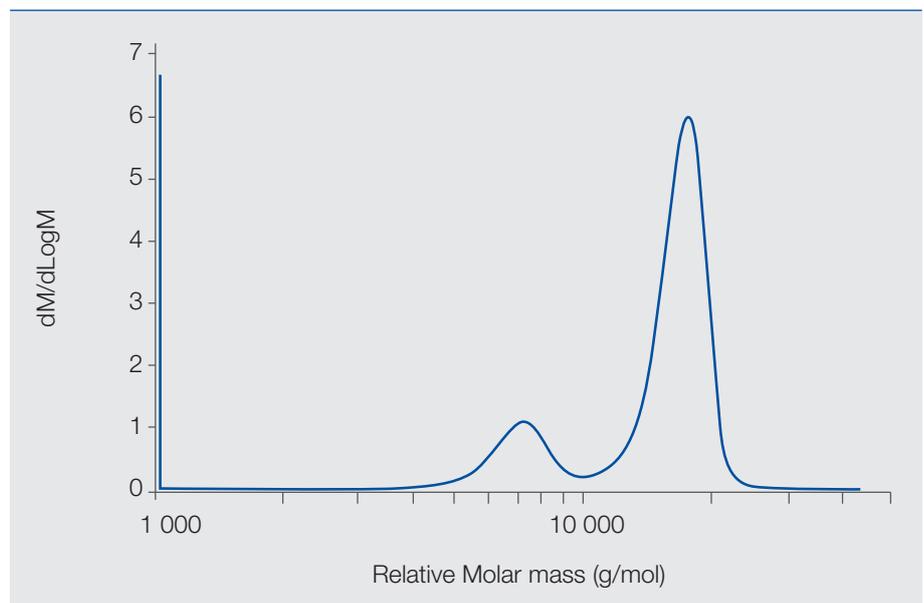


Figure 1: The above graph was generated using size exclusion chromatography (SEC), note that the smaller peak to the left represents diblock polymers.

Viscosity

Poloxamers, and Kolliphor® P 338 Geismar exhibits a thermoreversible gelling behavior that occurs as a function of temperature. At low concentrations, aqueous concentrations exhibit Newtonian flow properties and negligible viscosity alterations to that of water, however, at higher temperatures, the solutions begin to exhibit non-Newtonian flow behavior. An example of the viscosity curve is evident in Figure 2 below with the gel points indicated by the sharp increase in viscosity for a 20% w/w solution.

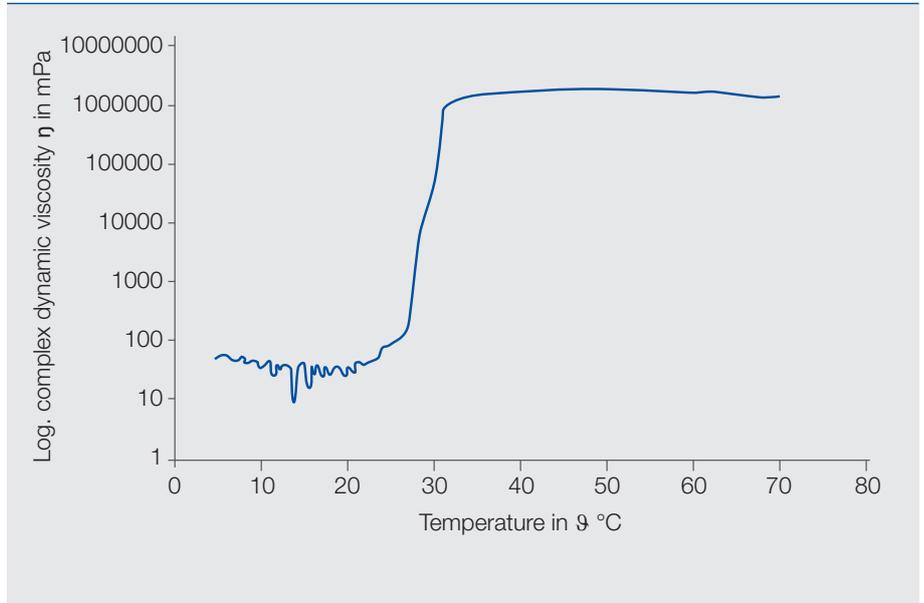


Figure 2:

HLB

The HLB value of Kolliphor® P 338 Geismar is approximately 27.

Critical Micelle Concentration (CMC)

The critical micelle concentration for Kolliphor® P 338 Geismar is published as $2.2 \cdot 10^{-5}$ mol/L @ 37 °C. Note that the CMC value decreases significantly as the temperature increases. Furthermore, due to the linear structure of the poloxamer, the value is difficult to ascertain as an inflection point using standard methods (such as Wilhelmy Plate Method).

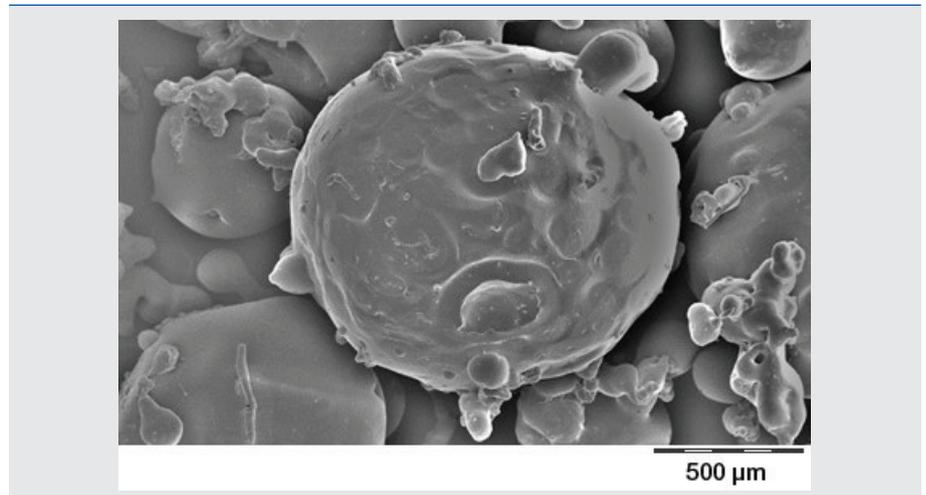
Solubility

Kolliphor® P 338 Geismar is highly soluble in water.

Note that Kolliphor® P 338 Geismar is significantly faster to dissolve in cold water.

Particle size

Kolliphor® P 338 Geismar exhibits spherical prill particles of a mean diameter of approximately 600 µm in size. An example of the size and morphology of these particles is shown in the scanning electron microscope image (SEM) show below in Figure X.



Cloud point

The cloud point for Kolliphor® P 338 Geismar is >100°C for a 1% and a 10% aqueous solution.

BHT

Poloxamers, and specifically Kolliphor® P 338 Geismar utilize 50 – 125 ppm BHT as an antioxidant – the protects the quality and performance of the P 338 Geismar in the multitude of pharmaceutical applications. The primary degradation mechanism is oxidation, and is typically monitored via the pH, hydroxyl value and molecular weight of the poloxamer.

3. Example application

Poloxamers are a widely used pharmaceutical ingredient in multitude of applications, most notably, as a dispersing agent, emulsifier, solubilizer, tablet and capsule lubricant, wetting agent, stabilizer for oral and topical suspensions, gelling agent in topical formulations.

Example Use Levels

Indication	Concentration (w/w%)
Gelling agent	15 to 50
Suspension stabilizer	0.1 to 5
Tableting	1 to 10
Wetting Agent	0.01 to 5
Emulsifier	1 to 5
Foaming agent	1 to 3
Plasticizer (matrix)	5 to 15

Solubilization

Kolliphor® P 338 Geismar can be used in a multitude of solubilization examples – more specifically the product may be a liquid solution, suspension or solid tablet. Given the low critical micelle concentration (CMC) stabilizing and solubilizing occurs at concentrations 1 to 2 orders of magnitude lower than for standard ethoxylated surfactants.

Skin delivery

Poloxamers as Gelling agents

Poloxamers can be used as gelling agents to build structure in a topical aqueous solution. Gels using Kolliphor® P 338 Geismar can exhibit thermoreversible behavior; they form gels which are liquids at room temperature but solidify upon contact with skin.

Phase	Ingredients	Chemical name	Description	Mass (Weight%)
A	Ethanol 200 Proof		Solvent	10
	Kollisolv® PG	Propylene Glycol	Solvent	10
	Kollicream® IPM	Isopropylmyristate	Tack reducer	2
	Glycerol		Solvent	5
B	Kolliphor® P 338 Geismar	Poloxamer 338	Gelling agent	15 – 20
	Deionized Water		Solvent	53 – 58

Gelling is a function of temperature, structure, and concentration of a given poloxamer. At high enough concentrations, poloxamers form multimolecular aggregates and micelles that aid in gelling. Notably, an increase in the amount of ethanol used in a formulation increases the gelling temperature of a given formulation. Kollicream® IPM reduces tackiness, resulting in an improved sensory experience.

Emulgel

At concentrations above 15%, Poloxamers 188 and 338 can be used to make gels and viscous emulsions by both emulsifying and forming phases and networks via the hydrophobic and hydrophilic interactions driven by PPO and PEO segments of the polymer, respectively.

Phase	Ingredients	Chemical name	Description	Mass (Weight%)
A	Ethanol 200 Proof		Solvent	10
	Kollisolv® PEG 400	Polyethylene Glycol 400	Solvent	15
	Glycerol		Solvent	5
B	Kolliphor® P 338 Geismar	Poloxamer 338	Gelling agent	18
C	Deionized Water		Solvent	42
D	Kollicream® 3 C	Cocoyl Caprylocaprate	Emollient	10

Kolliphor® P 338 Geismar helps emulsify the Kollicream® 3 C in this formulation, resulting in a translucent white gel with a cream-like structure visible underneath the microscope. Both Kolliphor® P 338 Geismar and Kollicream® 3 C have been shown to be very mild, in vitro and in vivo.

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. Product specification

The current version of the product specification is available on BASF WorldAccount* or from your local BASF sales representative.

6. Regulatory & Quality

Please refer to the individual document quality & regulatory product information (QRPI) which is available on BASF WorldAccount* and from your local sales representative. **The QRPI covers all relevant information including retest dates and storage conditions.**

7. Toxicology

The toxicological abstract is available on request.

8. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30631059	Kolliphor® P 338 Geismar	50424591	0.5 kg Plastic bottle
		50423936	80 kg Fibre drum

* BASF's commercial product number.

9. Publications

Publications including scientific posters are available on <http://pharmaceutical.basf.com/en.html>

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