Technical Information

Kolliphor® P 188 Geismar

Poloxamer Ph. Eur., Poloxamer USP/NF

Poloxamer for Pharmaceutical Use

March 2020 | **WF-No. DAWF-2019-0839**

BASF

We create chemistry

1. Introduction

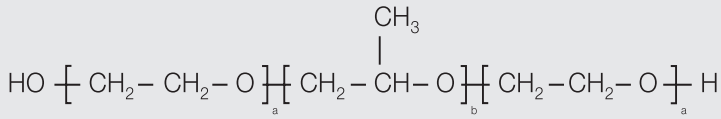
BASF's Kolliphor P grade poloxamers are white, coarse- grained powders with a waxy consistency. They contain an appropriate quantity of the antioxidant BHT.

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, P 188 succeeding the word Kolliphor® indicates a poloxamer with ca. 80% m/m PEO (P 188; 8x10= 80%) and approximately average molecular weight of PPO of 1800 (P 188; 18x100= 1800)

2. Technical properties

Structural formula

Kolliphor® P 188 Geismar is a block copolymer that is a synthetic copolymer of ethylene oxide and propylene oxide represented by the following chemical structure:



Where in a and b blocks have the following values:

Kolliphor®	Poloxamer	a	b
P 188	188	80	27

Appearance

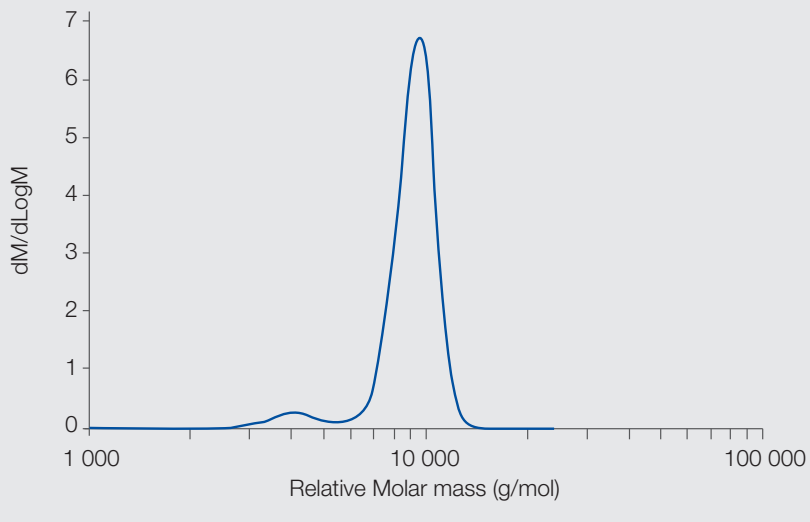
Kolliphor® P 188 Geismar is produced as a white to almost white prill/powder.

CAS Number

9003-11-6

Molecular Weight

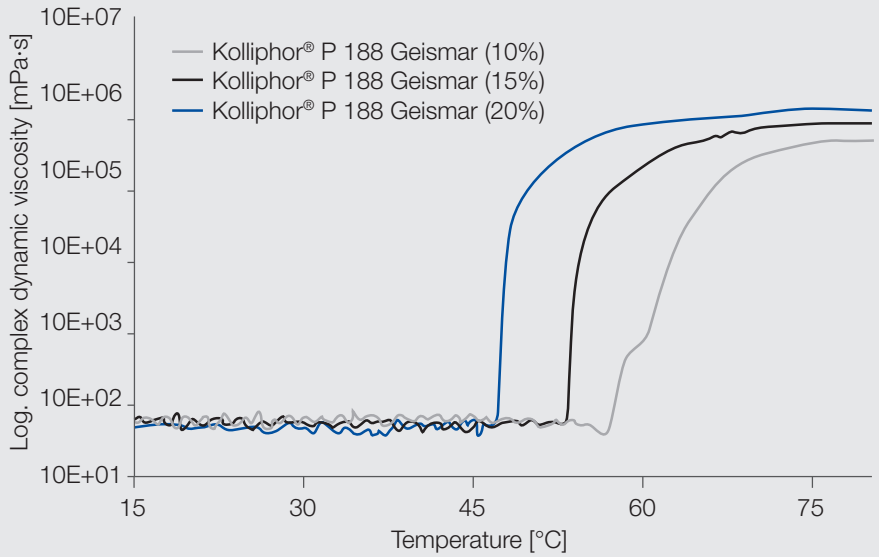
The average molecular weight for Kolliphor® P 188 Geismar is 7680 to 9510 g/mol. The product contains nominally 75 to 85 ethylene oxide units split between the two chains and 25 to 30 propylene oxide units, with a rough concentration of oxyethylene of 79.9 to 83.7 % based on the current monograph specification. An example of the molecular weight distribution for Kolliphor® P 188 Geismar is shown below in 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 188 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 clearly noted by the sharp increase in viscosity:

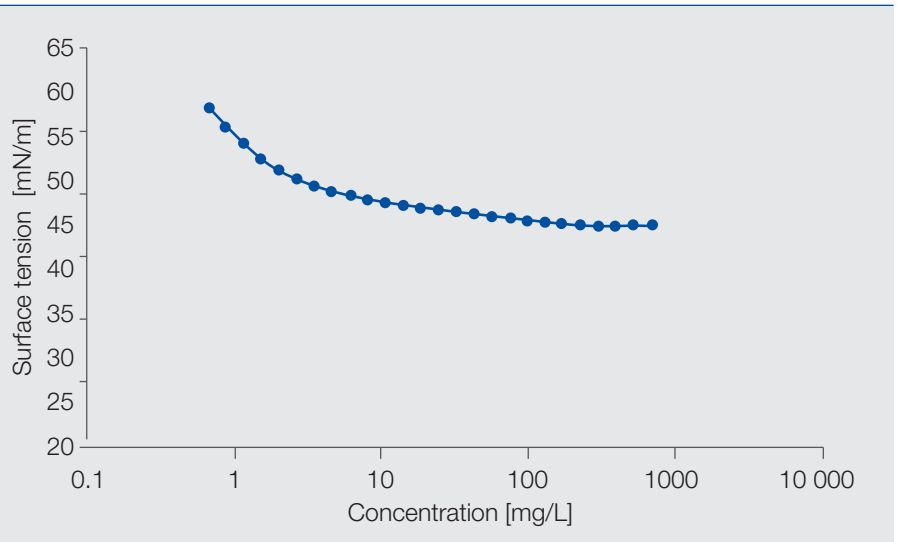


HLB

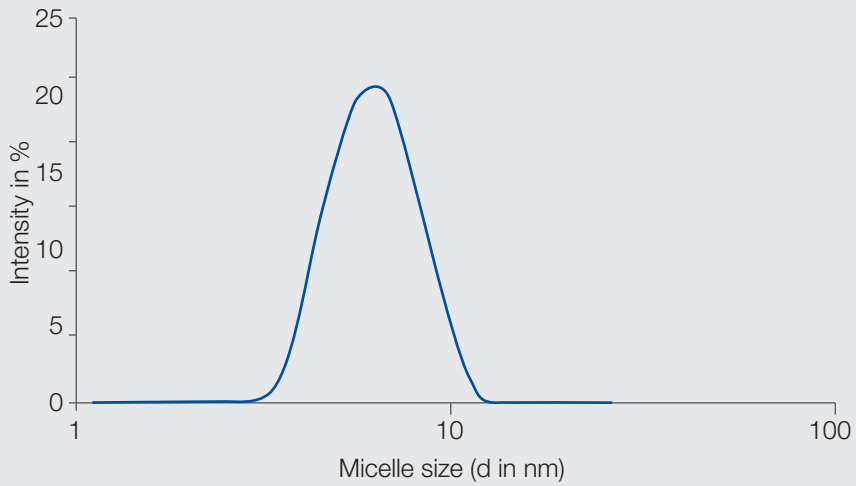
The HLB value of Kolliphor® P 188 Geismar is approximately 29.

Critical Micelle Concentration (CMC)

The critical micelle concentration for Kolliphor® P 188 Geismar is published as $4.8 \cdot 10^{-4}$ mol/L @ 37 °C (4.1 g/L). 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) an example of the surface tension for Kolliphor® P 188 Geismar as a function of concentration is shown below in Figure 3 (37 °C).



The micelle size is approximately 5 – 10 nm in diameter; this is shown in Figure 4 below as determined via laser diffraction:

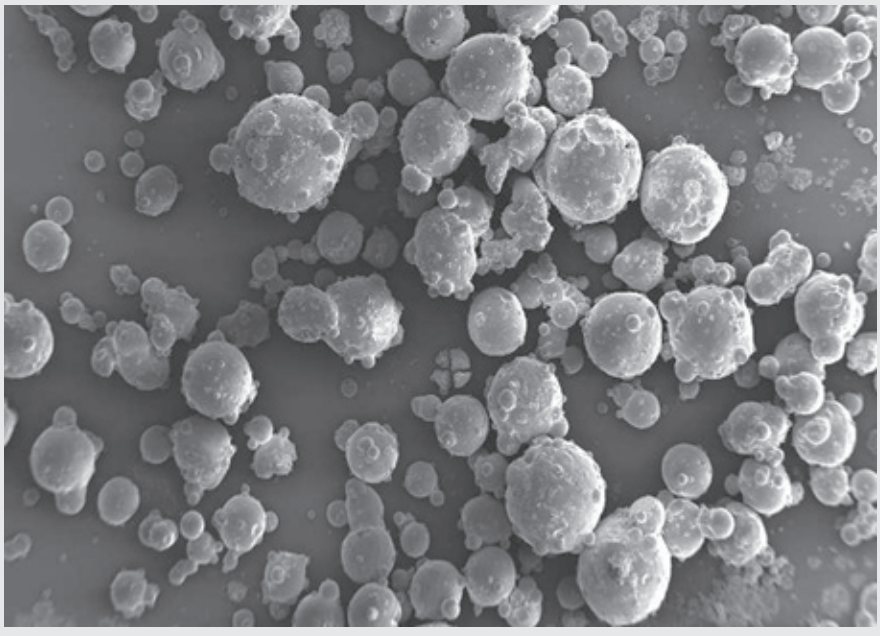


Solubility

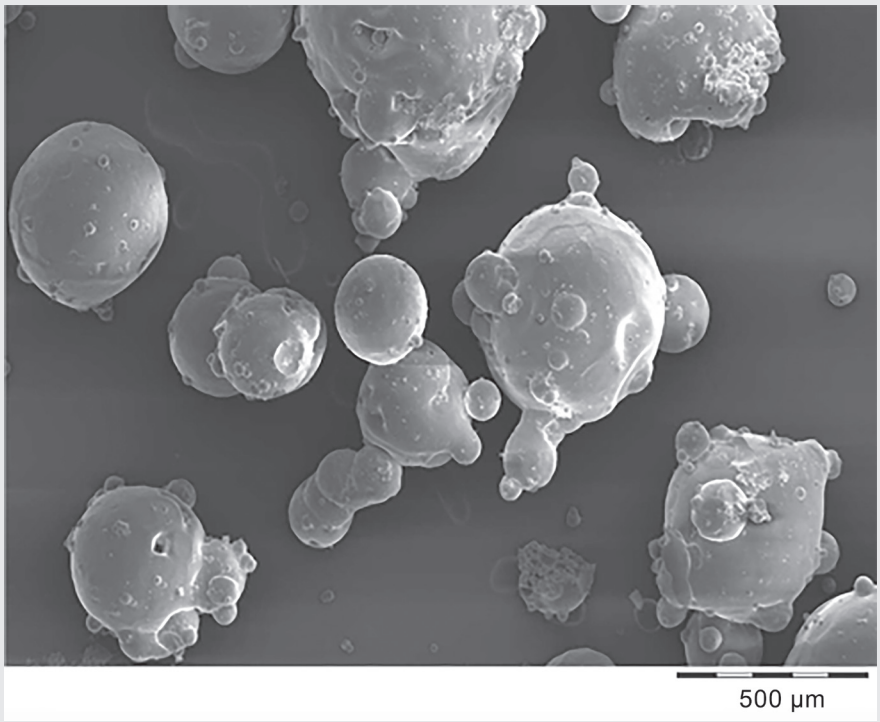
Kolliphor® P 188 Geismar is highly soluble in water.

Particle Size

Kolliphor® P 188 Geismar exhibits spherical prill particles of a mean diameter of approximately 500 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 5.



A closer image of the particles is shown below in Figure 6 at a higher magnification:



Cloud point

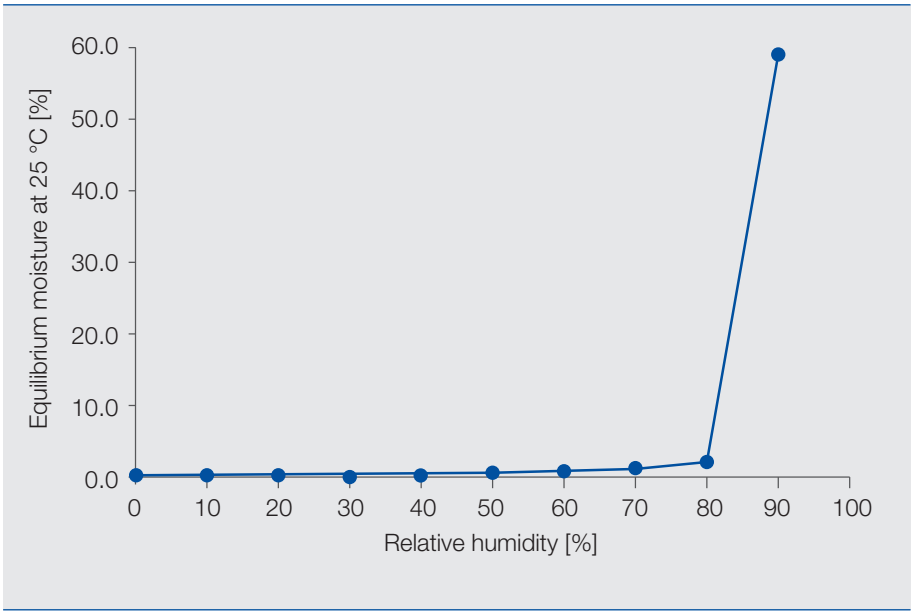
The cloud point for Kolliphor® P 188 Geismar is >100°C for a 1% and a 10% aqueous solution.

Density

The true density of Kolliphor® P 188 Geismar is approximately 1.06 g/cm^3.
The bulk density of Kolliphor® P 188 Geismar is approximately 0.56 g/cm^3.
The tapped density of Kolliphor® P 188 Geismar is approximately 0.61 g/cm^3.

Moisture sorption

The uptake of moisture for Kolliphor® P 188 Geismar is dependent on the relative humidity of the environment, at moisture levels above 80% (RH) significant moisture uptake is possible and shown in Figure 7 below:



BHT

Poloxamers, and specifically Kolliphor® P 188 Geismar utilize 50 – 125 ppm BHT as an antioxidant – the protects the quality and performance of the P 188 in the litany 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. Handling

Please refer to the individual Material Safety Data sheet (MSDS) for instructions on safe and proper handling and disposal.

4. 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 and shear protectant (for cell culture applications – please see Kolliphor® P 188 Bio).

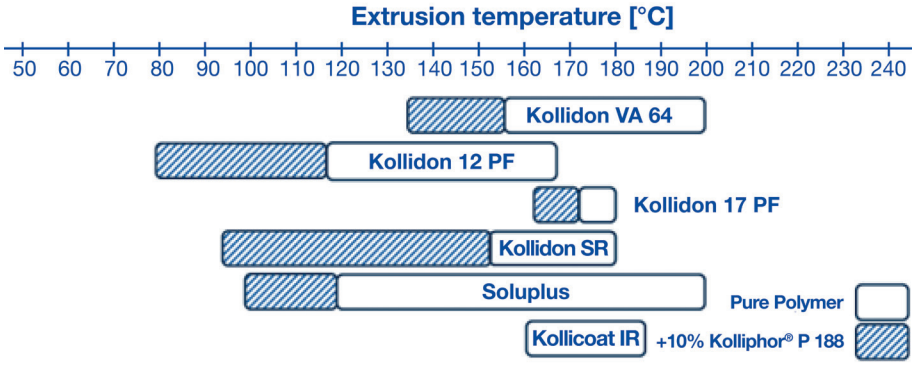
Example use levels

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 188 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.

In solid solutions, such as amorphous solid dispersions (ASDs) produced via hot melt extrusion (HME) and spray drying, Kolliphor® P 188 Geismar may be used as a plasticizing agent and/or solubilizer to further increase poorly water drug solubility in the matrix. As a plasticizer, it lowers the Tg of many polymers and allows for processing at lower shear rates and/or temperatures. An example of the processing temperature reduction is shown below in Figure 8.



Skin Delivery

Aerosol Foams

Growing in popularity, topical foams can sometimes be preferred over a cream due to their pleasing sensory application.

The four foam formulations below retain their shape upon application onto the skin, spreading easily and drying quickly.

Ingredients	Chemical name	Role	A	B	C	D
			(Weight%)			
Kolliwax® CSA 50	Cetostearyl Alcohol	Foam Stabilizer	3	3	3	3
Kolliphor® CS 12	Macrogol Cetostearyl Ether 12	Foaming Agent/ Emulsifier	0	0	6	6
Kolliphor® CS 20	Macrogol Cetostearyl Ether 20	Foaming Agent/ Emulsifier	5	6	0	0
Kollicream® 3C	Cocoyl Caprylocaprate	Emollient/ Solubilizer	3	3	3	3
Kolliphor® P 188 Geismar	Poloxamer 188	Foaming Agent	1	0	0	1
Deionized Water		Solvent	82	82	82	82
A 46	Propane/Isobutane	Propellant/Solvent	6	6	6	6

Foams made with Kolliphor® CS 12 tend to demonstrate a higher viscosity and stiffness than foams formulated with Kolliphor® CS 20. Additionally, poloxamers such as Kolliphor® P 188 Geismar or Kolliphor® P 407 Geismar can be added to formulations as needed to create richer, creamier foams. This richness is aided by the use of an aerosol.

Povidone-Iodine Foams

Kolliphor® P 188 Geismar acts as an effective emulsifier in the formation of non-aerosol foams for topical use. Foams of varying strengths can be created by altering the mass percent of API.

Phase	Ingredients	Chemical name	Role	Mass (Weight%)
A	PVP Iodine 30	Povidone-iodine	API	5 – 10
	Deionized Water		Solvent	87 – 92
	Kolliphor® P 188 Geismar	Poloxamer 188	Emulsifier	3

5. Safety data sheet

Safety data sheets are available on request and are sent with every consignment.

6. Retest date and storage conditions

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

7. Stability

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
30631536	Kollidon® P 188 Geismar	50424518	0.5 kg IP23
		50498319	25 kg Fibre drums
		50424307	102 kg Fibre drums

* BASF's commercial product number.

10. Publications

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

March 2020