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# Technical Information

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# Kolliphor<sup>®</sup> P 188 Bio

Poloxamer Ph. Eur., Poloxamer USP/NF, Polyoxyethylene (160) Polyoxypropylene (30) Glycol" JPE  
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.

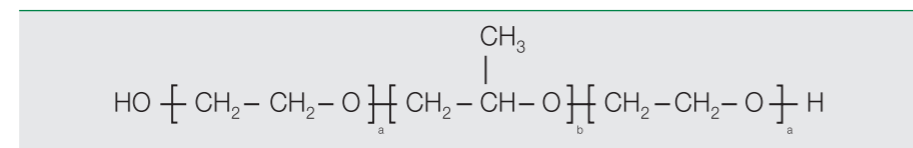
Poloxamers are ABA-type co-polymers of poly (ethylene oxide) (PEO=A) and poly (propylene oxide) (PPO=B). The approximate relative amount of PEO and the average molecular weight of the PPO are indicated in the name of the poloxamer. For example, P 188 succeeding the word Kolliphor® indicates a poloxamer with ca. 80% m/m PEO (P 188; 8x10= 70%) and approximately average molecular weight of PPO of 1800 (P 188; 18x100= 1800).

Kolliphor® P 188 Bio is designed for protection against shear stress in biologic drug manufacturing processes. It is also suitable as an excipient for parenteral formulations. Improvements in the manufacturing process and a validated RP-HPLC assay ensures the highest quality product for consistent performance and less variability versus other poloxamer 188 grades.

## 2. Technical properties

### Structural formula

The Kolliphor® P 188 Bio 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
Kolliphor® P 188 Bio	188	80	27

### Appearance

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



Figure 1: Appearance of Kolliphor® P188 Bio

### CAS Number

9003-11-6

### Solubility in water

Solubility in water at 25 °C measured gravimetrically is between 35-45 wt.%.

### Surface Tension

The static surface tension measured by the pendant drop method at 37 °C stabilizes after ca. 2 g/L.

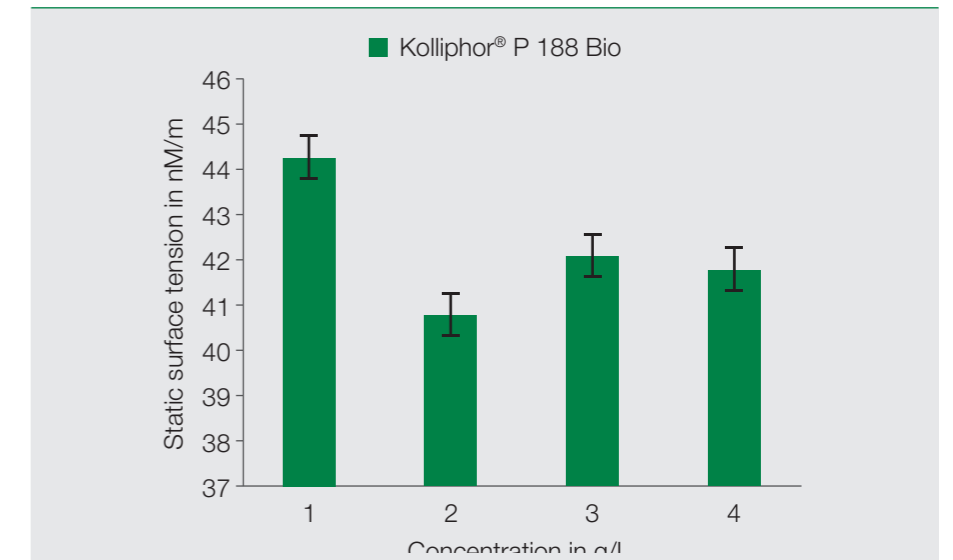


Figure 2: Surface tension as a function of concentration

### Molecular Weight

The average molecular weight for Kolliphor® P 188 Bio 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 Bio is shown below in Figure 3.

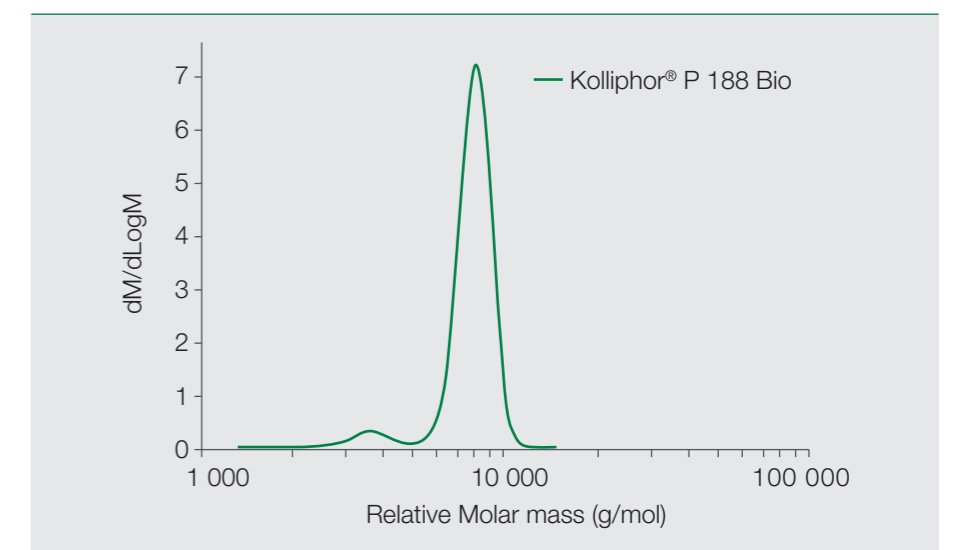


Figure 3: Size Exclusion Chromatogram of Kolliphor® P188 Bio

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 Bio 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 4 with the gel points clearly noted by the sharp increase in viscosity:

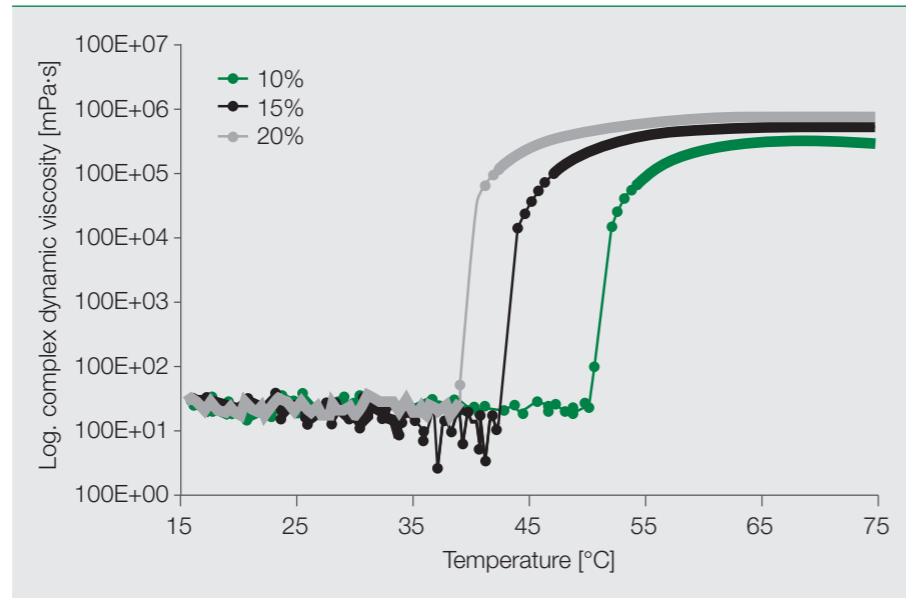


Figure 4: Viscosity changes of Kolliphor® P188 Bio solutions as function of temperature

### HLB

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

### Critical Micelle Concentration (CMC)

The critical micelle concentration for Kolliphor® P 188 Bio is ca.  $4.8 \cdot 10^{-4}$  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 Bio as a function of concentration at 37 °C is shown in Figure 5.

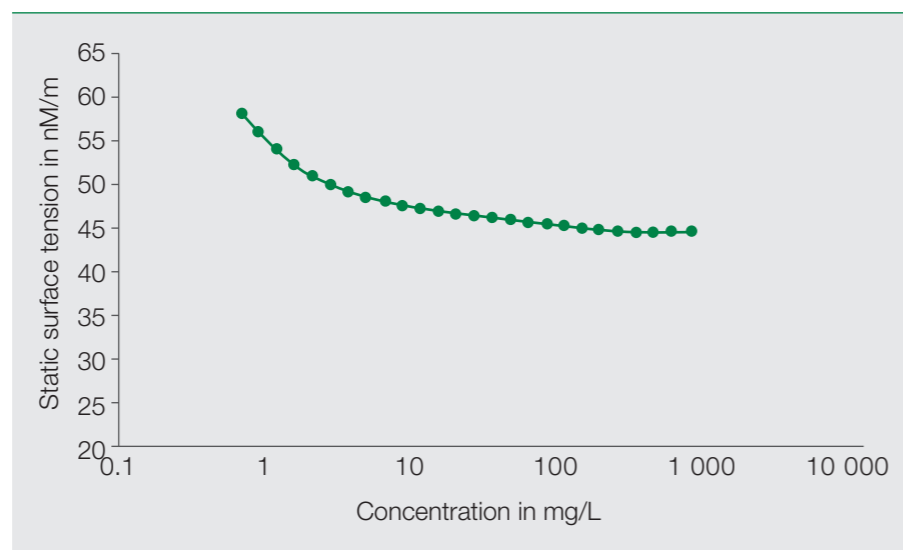


Figure 5: Surface tension as function of concentration

The micelle size is approximately 5 – 10 nm in diameter; this is shown in Figure 6 as determined via laser diffraction:

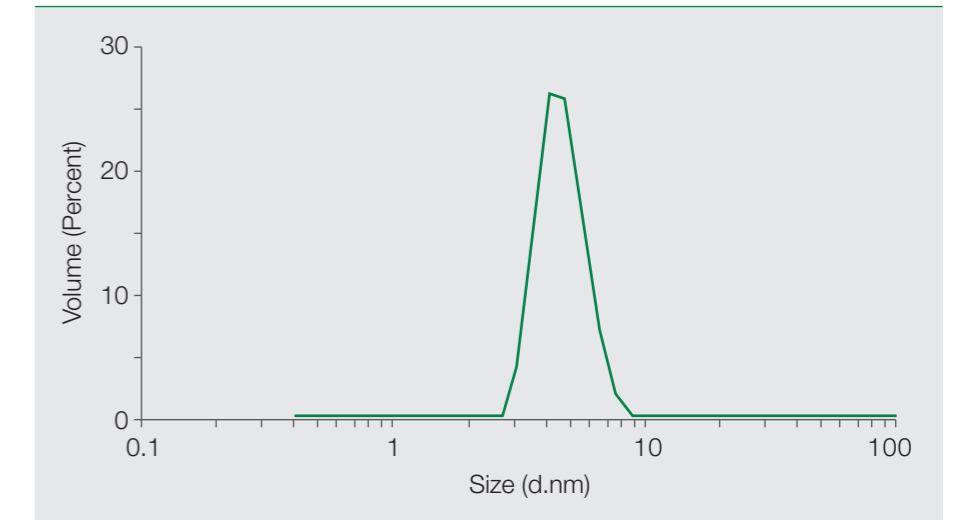
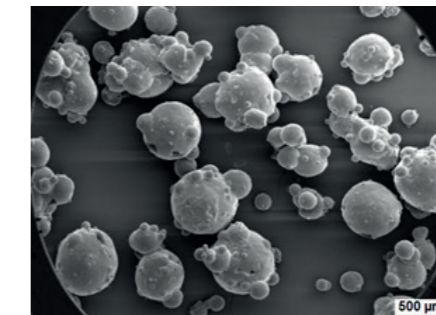


Figure 6: Micelle size as measured by laser diffraction

### Particle Size

Kolliphor® P 188 Bio 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).



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

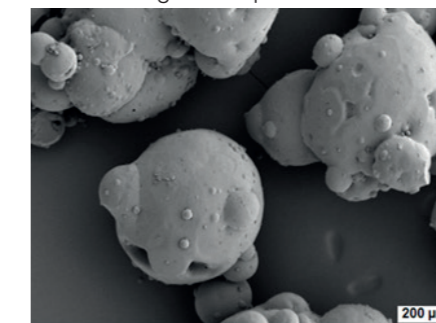


Figure 7: SEM images of Kolliphor® P188 Bio

### Cloud point

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

### Density

The bulk density of Kolliphor® P 188 Bio is approximately 0.56 g/cm<sup>3</sup>.

### Moisture sorption

The uptake of moisture for Kolliphor® P 188 Bio is dependent on the relative humidity of the environment, at moisture levels above 80% (RH) significant moisture uptake is possible and shown in Figure 8.

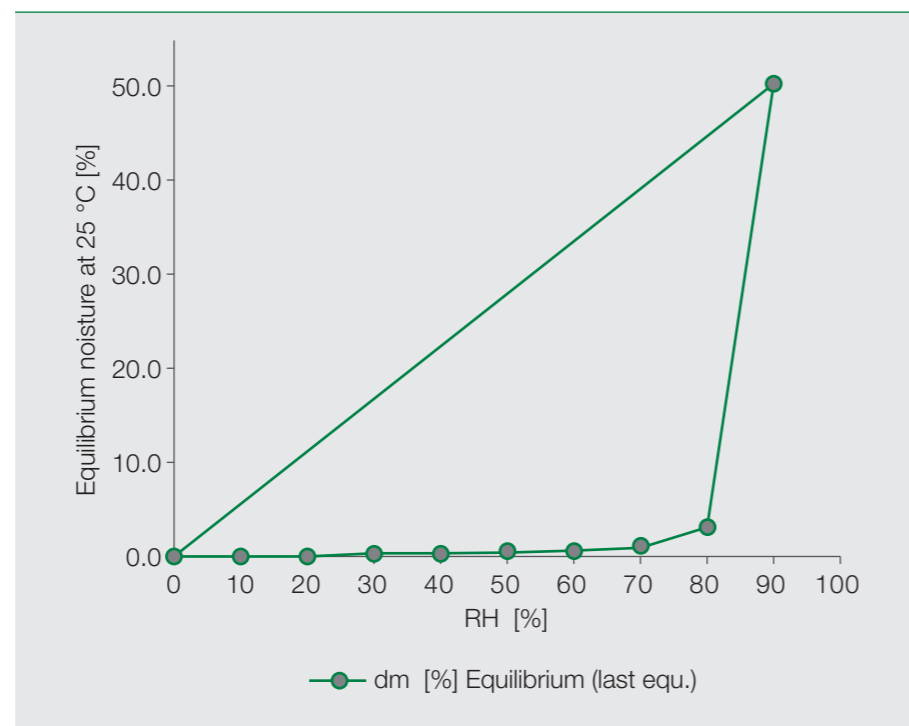


Figure 8: Moisture uptake as a function of relative humidity

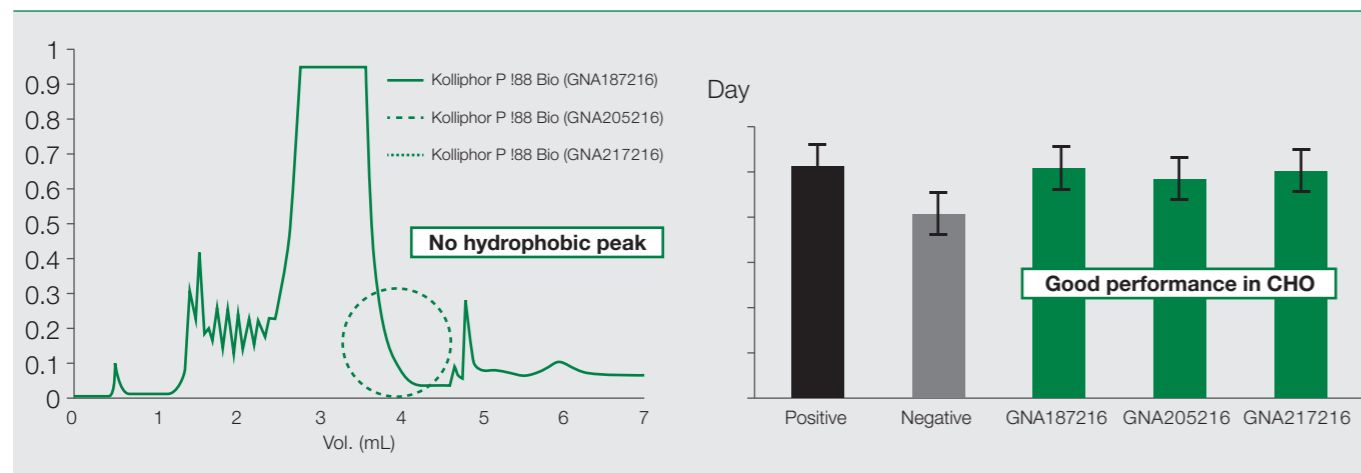
### BHT

Kolliphor® P 188 Bio utilizes 50 – 125 ppm BHT as an antioxidant – this 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



Three independent lots of Kolliphor® P 188 Bio were tested. RP-HPLC assay shows no hydrophobic peak at retention time of 4 mL (left). The cell culture assay shows cumulative CHO cell count on day four as expected for lots with good performance.

## 5. Safety data sheet

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

## 6. Retest date and storage conditions

36 months when stored in tightly closed containers at ambient conditions. Please refer to Quality & Regulatory Product Information (QRPI) for further details.

## 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
30631540	Kolliphor® P 188 Bio	50424596	0.5 kg Plastic bottle
		50519572	25 kg Plastic drums
		50519573	102 kg Plastic drums
		50519927	12.5 kg Plastic pail
		50519924	5 kg Plastic pail

\* BASF's commercial product number.

## 10. Publications

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

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