



# Biopharma Ingredients Portfolio

## High Quality Raw Materials for Biopharmaceutical Manufacturing

Biopharmaceutical manufacturing processes require high-quality raw materials delivered through a transparent and reliable supply chain, supported by experts. BASF Biopharma Ingredients is committed to meeting your requirements for every ingredient we supply to the biologics industry.

### Our Research & Development Team

- Designs new products that solve bioprocessing and formulation challenges
  - Drives new product development pipeline
- Provides support for a wide variety of other projects and topics

### Our Technical Teams

- Provide deep insights on surfactant chemistry and its use in bioprocessing
- Can access BASF Scientific Network, which is used for tackling the bigger challenges

### Our Quality & Regulatory Team

- Has a global & regional presence to support customer drug filing
- Works closely with manufacturing sites to ensure GMP compliance

# Biopharma Ingredients Portfolio

GMP Products Suitable for Use as Ingredients in Biopharma Manufacturing

Product	Monograph Quality	CAS #	Pack Sizes	Application		
				Upstream	Downstream	Formulation
<b>Kolliphor® P188 Bio</b> – poloxamer suitable for a broad range of applications, including cell culture shear protectant and excipient in final drug formulations	Ph. Eur., USP, JPE <sup>1</sup> , ChP <sup>2</sup>	9003-11-6	5 kg, 12.5 kg, 25 kg, 102 kg Plastic drum with double plastic liners	●	●	●
<b>Kolliphor® P188 Cell Culture</b> – poloxamer designed for functionality in a broader range of CHO & HEK culture systems	Ph. Eur., USP, JPE <sup>1</sup>	90003-11-6	102 kg Plastic drum with double plastic liners	●		
<b>Soluplus®</b> – anionic graft copolymer shown to provide excellent functionality in sensitive stem cell therapy systems <sup>3</sup>	N/A	402932-23-4	2.5 kg jerry can, 12.5 kg plastic drum, 25 kg fiberboard box with plastic liner	●		
<b>Kolliphor® SLS</b> – popular all-purpose anionic surfactant, also known as sodium dodecyl sulfate (SDS)	Ph. Eur., USP, JPE	151-21-3	25 kg fiberboard box with plastic liner		●	
<b>Kolliphor® HS-15</b> – surfactant designed as nonionic solubilizer, and redispersing agent for injectable formulations	Ph. Eur., USP	70142-34-6	50 kg steel drum			●
<b>Kolliphor® ELP</b> – surfactant designed as nonionic solubilizer, purified for use in sensitive applications including injectable formulations	Ph. Eur., USP	61791-12-6	60 kg steel drum			●

<sup>1</sup> The product meets the test requirements of the current monograph of "Polyoxyethylene (160) Polyoxypropylene (30) Glycol" JPE, containing BHT.  
<sup>2</sup> The product meets the acceptance criteria stipulated in the "Poloxamer 188" monograph of ChP 2020, applying the methods named in the product specifications.  
<sup>3</sup> Sakurai, M., Ishitsuka, K., Ito, R. et al. Chemically defined cytokine-free expansion of human haematopoietic stem cells. Nature 615, 127–133 (2023), WO2021/149799.



### Soluplus® Application Spotlight

Our R&D partnerships enable studies that work to establish protocols and overcome challenges to scale-up for future therapies. BASF Soluplus® was featured in a recent Nature publication<sup>3</sup> where it was shown to have advantages in the long-term ex-vivo expansion of HSCs in chemically defined media.

- + Manufactured in the USA and Germany according to IPEC-GMP guidelines
- + Enhanced packaging & testing requirements to meet biopharma requirements
- + History of use in pharmaceutical manufacturing
- + Regulatory documentation, registration, and submission support

# Introducing the Family of Poloxamers Designed for Biopharmaceutical Manufacturing

## Product Spotlight

Functionally, **Kolliphor® P188 Bio** was designed for performance consistency when used as a shear protectant in upstream CHO cell culture. However, Kolliphor® P188 Bio is suitable for use with many other cell types, including NSO, HEK293, and insect cell lines, at a wide variety of concentrations. This versatile surfactant is also known to decrease cell clumping upstream. The long history of use ensures protocols for downstream clearance and analytic testing afterwards are readily available.

The effects of shear stress during bulk fluid transfer can be mitigated with addition of poloxamer 188.

To further enable continuity of product use across the biomanufacturing process, Kolliphor® P188 Bio is manufactured in accordance with IPEC GMP guidelines, at a site inspected by the FDA. Kolliphor® P188 Bio is widely used in drug formulations, including proteins, peptides, antibodies, viral vectors, genes, and cells.



### Did you know...

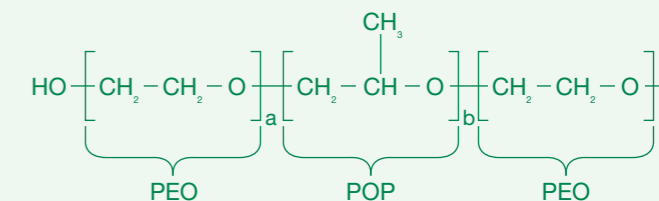
BASF Scientists were the original inventors\* of poloxamer chemistry, and we have been improving on it ever since!



	Kolliphor® P188 Bio	Kolliphor® P188 Cell Culture
Shear protection during upstream processing	●	●
Shear protection during intense upstream processing		●
Protection of drug substance during downstream processing	●	
Formulating a broad range of registered biologic therapies	●	

As critical parameters controlling shear protection performance continue to be investigated, BASF converts our new learning into innovative products enabling your bioprocess applications, now and into the future. **Kolliphor® P188 Cell Culture** was designed to target a lower average molecular weight while maintaining batch-to-batch consistency when used as a shear protectant in upstream CHO cell culture. However, Kolliphor® P188 Cell Culture is suitable for use with many other cell types across a variety of reactor types and process steps.

**Poloxamer 188** is a popular surfactant used across the various manufacturing process steps. It is a synthetic block copolymer of ethylene oxide and propylene oxide, solidified to form a white to almost prill/powder.



Chemical structure of poloxamer 188: a (EO units): 80; b (PO units): 27

\* US683227A, Donald R Jackson & Lester G Lundsted, Mixtures of novel conjugated polyoxyethylene-polyoxypropylene compounds, 1957.



### BASF Poloxamer Capabilities

- **World's largest GMP manufacturing network for poloxamers**
- Key site in Geismar, USA is IPEC-GMP compliant and EXCIPACT certified
- Poloxamer manufacturing capabilities at various scales with ability to meet critical specifications

### BASF Global Capabilities

- 6 Verbund sites & >200 other manufacturing sites
- Intelligent network of world-class production facilities to meet customer demands for quality, sustainability, and supply reliability
- Integrated supply chain and data exchange with customers, suppliers, and partners
- Transparency across entire supply chain

### Technical Applications Laboratory in Tarrytown, USA

- Small scale cell culture, molecular biology, and formulation instruments
- Provides application data and troubleshooting assistance for raw materials in BASF portfolio
- Routinely tests every batch of Kolliphor® P188 Bio and Kolliphor® P188 Cell Culture in multiple cell culture tests and for an additional trace metal panel
- Can take requests from customers for specific studies
- Has access to R&D materials and can connect customers in need of specific solutions not yet publicly available

# Imagine the Future

Partner with Chemistry



### Industry Advocacy

**We work with various industry organizations to help shape future best practices, guidance, and regulations**

### Did you know...

BASF is the leading manufacturer of poloxamer 188, with over 50 years experience in polymer chemistry. Our capability in manufacturing enables us to make new ingredients that can solve your toughest challenges.

**Ask us how!**



### Sustainability Commitment

**We aim to:**

- Reduce our CO<sub>2</sub> emissions by 25% by 2030
- Achieve Net Zero CO<sub>2</sub> emissions at BASF by 2050

PCF data available upon request



## Kolliphor® P188 Bio & Kolliphor® P188 Cell Culture: Transparency of Key Information

BASF is committed to providing you the technical, quality, and regulatory support you need to effectively manage this critical raw material. BASF makes available a broad range of quality and regulatory documents to our customers via our Virtual Pharma Assistant (VPA) tools. Because of the unique needs of the biopharma industry, there is also the possibility to support ad-hoc and customized requests for information not covered by our standard documentation. Furthermore, our commitment to closely partner with the biopharma industry enables us to be transparent about key information, which can equip the Quality and Regulatory stakeholders at our customers with a clear and confident view of how **Kolliphor® P188 Bio & Kolliphor® P188 Cell Culture** can mitigate risk for the biopharma manufacturer.

## Exceptional Quality & Regulatory Support



The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high-quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality-related questions.

A regional footprint secures quick and regional-specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations, we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

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