



We create chemistry

A **Toolbox** of **Surfactants** as Alternatives to Polysorbates for Biologic Formulations

Biopharma Ingredients

Biologics such as antibodies, therapeutic proteins, viral-vector gene therapies and vaccines are large and complex molecules and their function is highly dependent on their structure. To ensure safe and effective drugs are delivered to patients, surfactants are added to biologic formulations to protect the drugs against environmental stresses and damage. Currently, most biologics are formulated with either polysorbate 20 or polysorbate 80 and it is well-documented that polysorbates can degrade in final formulations, which can lead to safety concerns for patients and reduced protection for the biologic. At BASF, we provide a toolbox of surfactants that can be used as alternatives to polysorbates for biologic formulations.

Kolliphor® P188 Bio, Kolliphor® HS 15 and Kolliphor® ELP

- ✓ Additional tools to tackle formulation challenges posed by new classes of biologics
- ✓ History of prior use in approved parenteral drugs
- ✓ Manufactured in the USA and Germany according to cGMP
- ✓ Enhanced packaging and testing to meet the needs of biopharma manufacturing
- ✓ Regulatory documentation, registration and submission support
- ✓ Compendial compliance, non-clinical safety data and Drug Master File

Inspiring Medicines for Better Lives

 BASF_Pharma

 BASF Pharma Solutions

www.pharma.basf.com

Products

Biologic formulations require the most stringent requirements to be met in order to ensure patient safety and the optimal performance of the drug. At BASF, we provide a toolbox of surfactants that can be used as alternatives to polysorbates for formulating biologics including antibodies, therapeutic proteins, viral-vector gene therapies and vaccines.

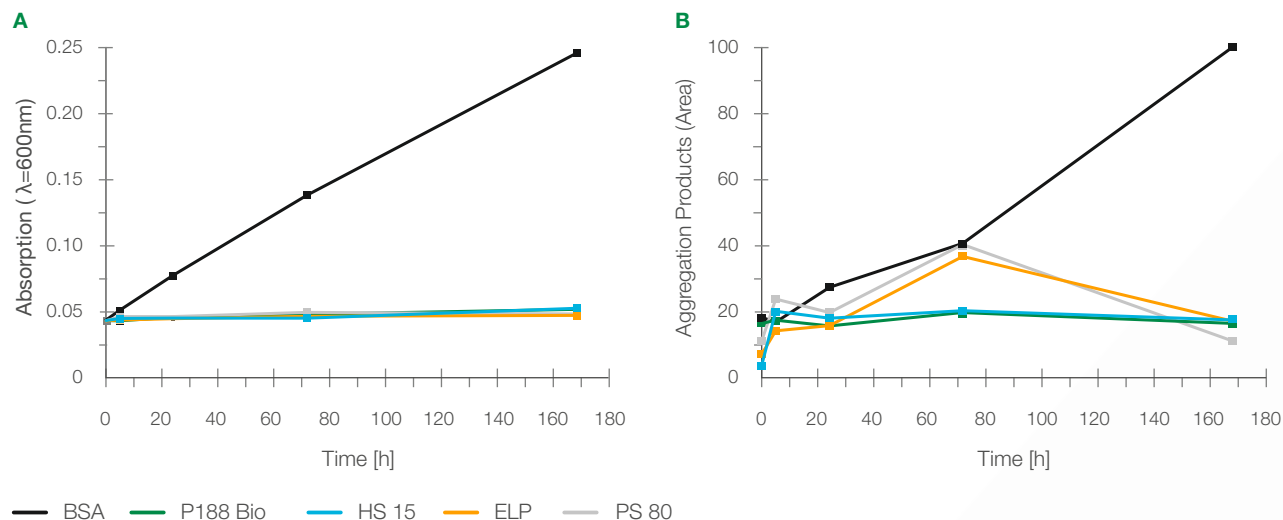
Customer Support

BASF surfactants are produced by qualified and experienced personnel in line with IPEC-PQG GMP quality and regulatory standards for use in the formulation of biologics for parenteral administration. Additionally, we enable our customers to tackle their formulation challenges rapidly and efficiently by providing industry-leading technical expertise, and a deep and profound understanding of the chemistry of our surfactants.



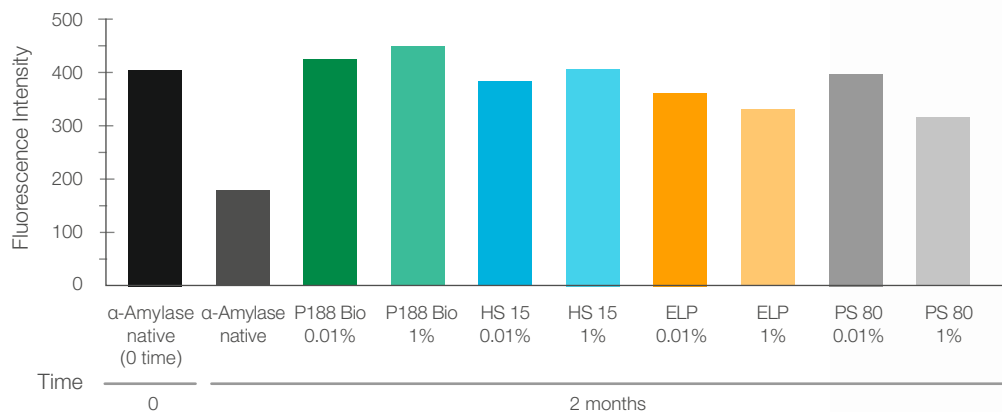
Product	Functionality	HLB	Monograph Title	FDA IID Listing
Kolliphor® P188 Bio	Non-Ionic Surfactant	29	Poloxamer 188 (Ph. Eur.)	Yes
			Poloxamer 188 (USP)	
Kolliphor® HS 15	Non-Ionic Surfactant	15	Macrogol 15 Hydroxystearate (Ph. Eur.)	Yes
			Polyoxyl 15 Hydroxystearate (USP)	
Kolliphor® ELP	Non-Ionic Surfactant	12-14	Macrogolglycerol Ricinoleate (Ph. Eur.)	Yes
			Polyoxyl-35-Castor Oil (USP)	

Product Details	Kolliphor® P188 Bio	Kolliphor® HS 15	Kolliphor® ELP
Manufacturing Standard	IPEC-PQG GMP	IPEC-PQG GMP	IPEC-PQG GMP
Country of Origin	USA	Germany	Germany
Compendial Compliance	Ph. Eur., USP, JPE	Ph. Eur., USP	Ph. Eur., USP
cGMP Quality	●	●	●
Higher Purity	●		●
Parenteral Grade	●	●	●
CoA	●	●	●
Drug Master File	●	●	●
Non-Clinical Safety Data	●	●	●
Sterilization Data	●	●	●
Technical Support	●	●	●
Regulatory Submission Support	●	●	●
Microbial Testing	●	●	●
Endotoxin Testing	●	●	●
Premium Packaging	●	●	●



Evaluation of Mechanical Stress

Mechanical stress was evaluated by stirring the model protein BSA for 7 days with Kolliphor® P188 Bio, Kolliphor® HS 15 and Kolliphor® ELP, compared to polysorbate 80. Absorbance measurements show a decrease in both (A) the formation of visible aggregates, and (B) the formation of sub-visible aggregates, thereby demonstrating a clear stabilization effect seen from the BASF surfactants.



Evaluation of Oxidative Stress

The α-amylase activity assay evaluates oxidative damage after 2 months of incubation with Kolliphor® P188 Bio, Kolliphor® HS 15 and Kolliphor® ELP, compared to polysorbate 80. α-Amylase is an enzyme known to be sensitive to oxidation, and after a 60-day incubation the activity assay indicates the surfactants are not contributing to oxidative degradation.

Kolliphor® P188 Bio

Poloxamer 188 has a prior history of use in the final formulation of marketed biologics and is the only surfactant besides polysorbates to have previously been used in biologic formulations. It is a versatile surfactant that has been used to stabilize different categories of biologics including antibody, therapeutic protein, peptide and viral-vector gene therapy products. Kolliphor® P188 Bio is a high purity poloxamer 188 that is designed to meet your needs in quality, consistency, and performance in the formulation of parenteral biologic drugs.

Kolliphor® HS 15 and Kolliphor® ELP

Polyoxyl 15 Hydroxystearate and Polyoxyl-35-Castor Oil are non-ionic surfactants with a prior history of use in the final formulation of marketed parenteral small molecule drugs. Kolliphor® HS 15 and Kolliphor® ELP are produced to meet the quality, consistency and performance needs of the biopharma industry. They are additional tools to tackle the formulation challenges that new formats of biologics can offer and provide formulators with new options to find the ideal formulations to maximize the performance of their biologics.



We create chemistry

Contact us and get your sample today!

pharma-solutions@basf.com

www.pharma.basf.com

This document, or any information provided herein does not constitute a legally binding obligation of BASF and has been prepared in good faith and is believed to be accurate as of the date of issuance. Unless expressly agreed otherwise in writing in a supply contract or other written agreement between you and BASF:

- (a) To the fullest extent not prohibited by the applicable laws, BASF EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY FACT OR LAW, INCLUDING ANY IMPLIED WARRANTIES, REPRESENTATIONS OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, NON-INFRINGEMENT, AND ANY REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES, ARISING FROM STATUTE, COURSE OF DEALING OR USAGE OF TRADE and BASF HEREBY EXPRESSLY EXCLUDES AND DISCLAIMS ANY LIABILITY RESULTING FROM OR IN CONNECTION WITH THIS DOCUMENT OR ANY INFORMATION PROVIDED HEREIN, including, without limitation, any liability for any direct, consequential, special, or punitive damages relating to or arising therefrom, except in cases of (i) death or personal injury to the extent caused by BASF's sole negligence, (ii) BASF's willful misconduct, fraud or fraudulent misrepresentation or (iii) any matter in respect of which it would be unlawful for BASF to exclude or restrict liability under the applicable laws;
- (b) Any information provided herein can be changed at BASF's sole discretion anytime and neither this document nor the information provided herein may be relied upon to satisfy from any and all obligations you may have to undertake your own inspections and evaluations;
- (c) BASF rejects any obligation to, and will not, automatically update this document and any information provided herein, unless required by applicable law; and
- (d) The user is responsible for confirming that the user has retrieved the most current version of this document from BASF as appropriate

© 2021 BASF

If you have any further questions or need additional support, please contact your BASF representative.