



We create chemistry

High Purity Excipients for Ophthalmic Formulation



BASF offers a portfolio of



- ✓ IID-listed excipients for a variety of ophthalmic formulations, such as solutions and emulsions



- ✓ Non-ionic surfactant chemistries suitable for ophthalmic uses



- ✓ Endotoxin and microbial testing



- ✓ Highly purified excipients that allow for preservative-free formulation



- ✓ Proven stability after sterile filtration, autoclave sterilization, and heat-stress cycling

All ophthalmic dosage forms require critical care of excipient sterility. BASF offers a wide range of high-quality solubilization excipients that are manufactured and packaged to high quality and regulatory standards.

- ✓ Excipients manufactured according to IPEC-PQC GMP
- ✓ Compendial compliance covering current and proposed major global pharmacopoeia standards
- ✓ Regulatory and non-clinical safety data documentation available
- ✓ Endotoxin & microbial testing
- ✓ Elemental impurity limits as per ICH Q3D
- ✓ Stability studies as per ICH guidelines



Kolliphor® HS 15

- ✓ Highly effective non-ionic solubilizer and emulsifier
- ✓ Already approved in IID for ophthalmic emulsions

Product Information

Monograph	Macrogol 15 Hydroxystearate (Ph. Eur.), Polyoxyl 15 Hydroxystearate (USP/EP)
CAS number	70142-34-6
Physical Form	Yellowish paste at room temperature, liquid at approx. 30 °C
pH (10 % water)	6 – 7
Hydrophilic Lipophilic Balance (HLB)	14 – 16
Critical Micelle Concentration	0.005% – 0.02%
Total aerobic microbial count (TAMC)	≤ 100 CFU/g
Total combined yeasts and molds count (TYMC)	≤ 10 CFU/g

Packaging

Article number

Package size

50668111

5 kg steel drum

50581346

50 kg steel drum

Kolliphor® ELP

- ✓ Highly purified Kolliphor® EL grade
- ✓ Non-ionic solubilizer and emulsifier with excellent compatibility with other ingredients
- ✓ Especially suitable for formulations containing extremely sensitive APIs
- ✓ Already approved in the IID for ophthalmic solutions and drops

Product Information

Monograph

Macrogolglycerol ricinoleate (Ph. Eur.), Polyoxyl 35 Castor Oil (USP/EP)

CAS number

61791-12-6

Physical Form

Paste at room temperature, liquid at approx. 30 °C

pH (10 % water)

5 – 7

Hydrophilic Lipophilic Balance (HLB)

14 – 16

Critical Micelle Concentration

0.02%

Total aerobic microbial count (TAMC)

≤ 100 CFU/g

Total combined yeasts and molds count (TYMC)

≤ 10 CFU/g

Packaging

Article number

Package size

50667956

5 kg steel drum

50251534

60 kg steel drum

Our service offer

For our parenteral excipients we provide comprehensive documentation including toxicological assessments, regulatory & quality packages, certificates and more.

Please contact us regarding your specific applications and needs:

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