

Empowering Innovation

Innovative biomaterials for parenteral controlled release and medical devices

Resomer®



 **EVONIK**
POWER TO CREATE

30 years of RESOMER®

The history of RESOMER® is the story of an ambitious vision: To help achieve a better quality of life for people.

For the last 30 years, this vision led our scientists to never be satisfied with the status quo. It pushed them to raise the bar higher and ever higher. It made them give all the passion and expertise they had into making RESOMER® the success story it is and will continue to be.

But most of all it made them listen very carefully to you, our customers. **Because your needs always were and always will be the major driving force for our RESOMER® team.**



Offering endless opportunities:

Evonik offers bioresorbable polymers that not only set industry standards, **but also open new directions for therapy development.**



Proven high-tech products

PERFORMANCE ENHANCED BY TECHNOLOGY:

Evonik offers a broad range of biodegradable polymers for medical device, parenteral controlled drug release and regenerative medicine applications.

The polymers we develop and manufacture expand the possibilities for improved drug delivery and innovative medical devices.

Semi-crystalline polymers such as homo- and copolymers of L-lactide, D,L-lactide,

glycolide, caprolactone, dioxanone are typically used to produce medical devices such as orthopedic and soft tissue fixation devices.

Amorphous polymers such as homo- and copolymers of D,L-lactide and glycolide are the key excipients for many sustained release drug delivery systems. They improve targeting combined with precise delivery timing – for one or even several active pharmaceutical ingredients.

Polymer properties that are outstanding

COMBINING ADOPTABILITY AND STABILITY:

The main benefit of RESOMER® is that it is safely resorbed by the body after implantation or injection.

By modification of molecular weight and polymer composition, the degradation rate and mechanical stability can be adopted to the individual requirements of the application.

Degradable polymers do not pose any handling problems with regard to processing, storage or safety. They are available in granular form – mainly for medical applications – or as a powder for pharmaceutical formulations.

Stability studies are available, showing the long-term shelf life of the polymers under proper storage conditions.





Highest process standards

CONSTANTLY IMPROVING THE STATUS QUO:

The polymers are produced by complex processes which have been optimized to assure consistent quality.

One key strength is Evonik's purification process that yields material with very low residual monomer, which is essential for thermal processing and the controlled delivery of proteins and peptides.

Evonik is your partner through your entire product life cycle. We support you during the development process and during the

commercial manufacturing with a reliable supply of high quality products. Our manufacturing sites in the US and in Germany follow the highest manufacturing and safety standards.

You can determine the scope of our involvement and always count on us for reliable supply – around the world and around the corner.



Quality that you can rely on

DELIVERING CERTIFIED PRODUCTS:

Evonik places particular emphasis on the quality of its products. All materials are carefully tested prior to further processing.

All products are subjected to continuous quality control measures during the production process which complies with GMP guidelines. A certificate of analysis is issued for every batch produced.

All plant operations meet relevant Environment, Health, and Safety (EHS) requirements.

All our business activities are DIN ISO 9001 certified. Our products are covered by a DMF or MAF, filed with the FDA and are updated annually.

Technical documentation can be provided for all non-US registrations on request.





Medical application

DELIVERING SPECIALIZED PERFORMANCE:

The RESOMER® product portfolio contains polymers for the production of bioresorbable implants, medical devices and tissue engineering solutions for either repairing bones, replacing body functions or helping organs repair themselves.

These medical devices can also be combined with drugs for controlled release over time.

Bioresorbable plates and screws for trauma and orthopedic applications, bioabsorbable stents and coatings for next generation cardiovascular treatments are just a few products made by our RESOMER® family of bioresorbable polymers.

The advantages are:

- proven safety track record,
- no adverse reactions,
- complete metabolization,
- easy processing.



Medical device application laboratories

ENGINEERED EXCELLENCE WITH RESOMER®:

Our bioresorbable polymers help the medical device industry discover new ways to use the body's own regenerative and repair potential.

With our medical device application laboratories in Germany and China, we help our customers not only with reliable supply of materials but also with support on how to best use RESOMER® polymers for their specific design and production needs.



OUR EXPERTISE INCLUDES:

- Injection-molding
- Extrusion
- Selection of the most suitable polymer for the application
- Characterization of production process conditions for successful design and scale-up
- Manufacturing of technical samples for feasibility studies

WE HELP YOU DESIGN AND SCALE UP MEDICAL DEVICES FASTER.





Pharmaceutical application

ENHANCING THERAPEUTICAL POSSIBILITIES:

RESOMER[®] is synonymous with parenteral controlled release delivery systems that keep pushing the **therapeutic frontier, from nanoparticles to drug-eluting films and particles.**

RESOMER[®] polymers offer scientists more possibilities for targeting and timing of therapies with greater precision at lower dosages and with more efficacy and fewer side-effects.

A large number of controlled release as well as long-acting medication delivery formulations developed by and with us are making a difference in millions of patient lives.

Besides supplying the bioresorbable polymers, we can work with you in developing the right and extended depot formulation and manufacture sophisticated injectable products.

Evonik's proprietary FormEZE[™] delivery technology, for instance, can deliver concentrated microparticle suspensions via small needles (25-27G) for enhanced bio-availability and greater patient comfort, including easier self-administration.



RESOMER® Select – Your vision realized

TRULY EMPOWERING INNOVATION:

Our understanding of APIs, delivery systems and manufacturing processes enables us to develop novel polymers which will allow you to manufacture innovative drug delivery systems or medical devices.

In the formulation of customized polymers we look at monomers and their respective ratios, polymer chain end groups, PEG contents, and targeted specifications, to meet your exact needs.

As partner to the pharma and medical device industry, we are privy to the constant advances in API development but also the expanding knowledge of how the body works and finds ways of repairing itself. Our vocation is to fill the technology gap between the potential solutions our customers develop and the actual solutions that help patients get better sooner and with fewer trade-offs.

THE AREAS WE LOOK FORWARD TO EXPLORING WITH YOU ARE:

SMART BIOMATERIALS:

- dynamically responsive biomaterials,
- conductive polymers,
- biomaterials for cellular production,
- biomaterials and scaffolding for bone regeneration,
- biomaterials and scaffolding for neural regeneration,
- cardiovascular biomaterials,

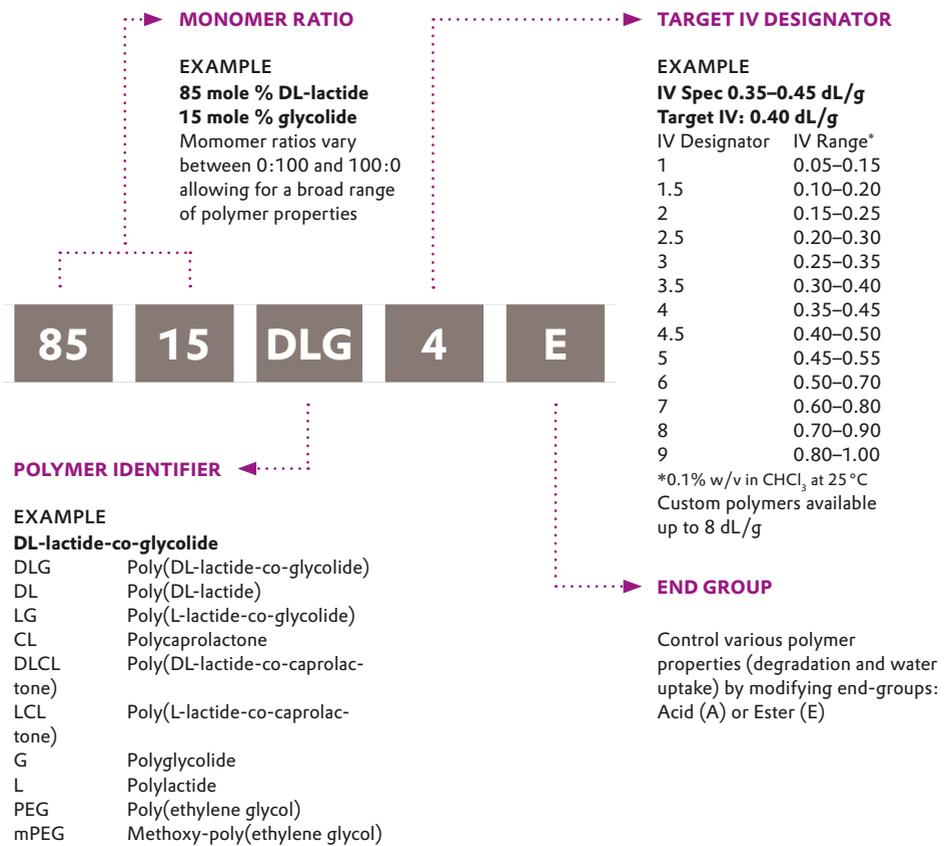
AND DRUG DELIVERY SYSTEMS:

- nanomaterials,
- implants,
- high-potency API delivery,
- nanomaterials,
- ophthalmic biomaterials,
- orthopedic biomaterials,
- dental biomaterials,
- tissue engineering.

Besides supplying the bioresorbable polymers, we can work with you in developing the right and extended depot formulation and manufacture sophisticated injectable products.



RESOMER® Select naming



RESOMER[®] product range

MEDICAL DEVICE APPLICATION

Product name	IV [dL/g]
Poly(L-lactide)	
RESOMER [®] L 206 S	0.8–1.2
RESOMER [®] L 207 S	1.5–2.0
RESOMER [®] L 209 S	2.6–3.2
RESOMER [®] L 210 S	3.3–4.3
Poly(L-lactide-co-D,L-lactide) 70:30	
RESOMER [®] LR 704 S	2.0–2.8
RESOMER [®] LR 706 S	3.3–4.2
RESOMER [®] LR 708	5.7–6.5
Poly(L-lactide-co-glycolide) 82:18	
RESOMER [®] LG 824 S	1.7–2.6
Poly(L-lactide-co-glycolide) 85:15	
RESOMER [®] LG 855 S	2.5–3.5
RESOMER [®] LG 857 S	5.0–7.0
Poly(L-lactide-co-ε-caprolactone) 70:30	
RESOMER [®] LC 703 S	1.3–1.8
Poly(D,L-lactide)	
RESOMER [®] R 207 S	1.3–1.7
Poly(dioxanone)	
RESOMER [®] X 206 S	1.5–2.2*
Poly(caprolactone)	
RESOMER [®] C 209	0.8–1.2
RESOMER [®] C 212	1.13–1.38

Inherent viscosity is measured at 0.1 % w/v in CHCl₃ at 25 °C with a Ubbelohde size 0c glass capillary viscometer

* Inherent viscosity is measured at 0.1 % w/v in HFIP at 30 °C with a Ubbelohde size 0b glass capillary viscometer

CONTROLLED RELEASE APPLICATION

Product name	IV [dL/g]
Poly(D,L-lactide)	
RESOMER® R 202 S	0.16–0.24
RESOMER® R 202 H	0.16–0.24
RESOMER® R 203 S	0.25–0.35
RESOMER® R 203 H	0.25–0.35
RESOMER® R 205 S	0.55–0.75
Poly(D,L-lactide-co-glycolide) 50:50	
RESOMER® RG 502	0.16–0.24
RESOMER® RG 502 H	0.16–0.24
RESOMER® RG 503	0.32–0.44
RESOMER® RG 503 H	0.32–0.44
RESOMER® RG 504	0.45–0.60
RESOMER® RG 504 H	0.45–0.60
RESOMER® RG 505	0.61–0.74
Poly(D,L-lactide-co-glycolide) 65:35	
RESOMER® RG 653 H	0.32–0.44
Poly(D,L-lactide-co-glycolide) 75:25	
RESOMER® RG 752 H	0.14–0.22
RESOMER® RG 752 S	0.16–0.24
RESOMER® RG 753 H	0.32–0.44
RESOMER® RG 753 S	0.32–0.44
RESOMER® RG 755 S	0.50–0.70
RESOMER® RG 756 S	0.7–1.0
RESOMER® RG 750 S	0.8–1.2
Poly(D,L-lactide-co-glycolide) 85:15	
RESOMER® RG 858 S	1.3–1.7

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RESOMER® = reg. trademark of Evonik Industries AG and its subsidiaries

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EVONIK NUTRITION & CARE GmbH

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Pharma Polymers & Services

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