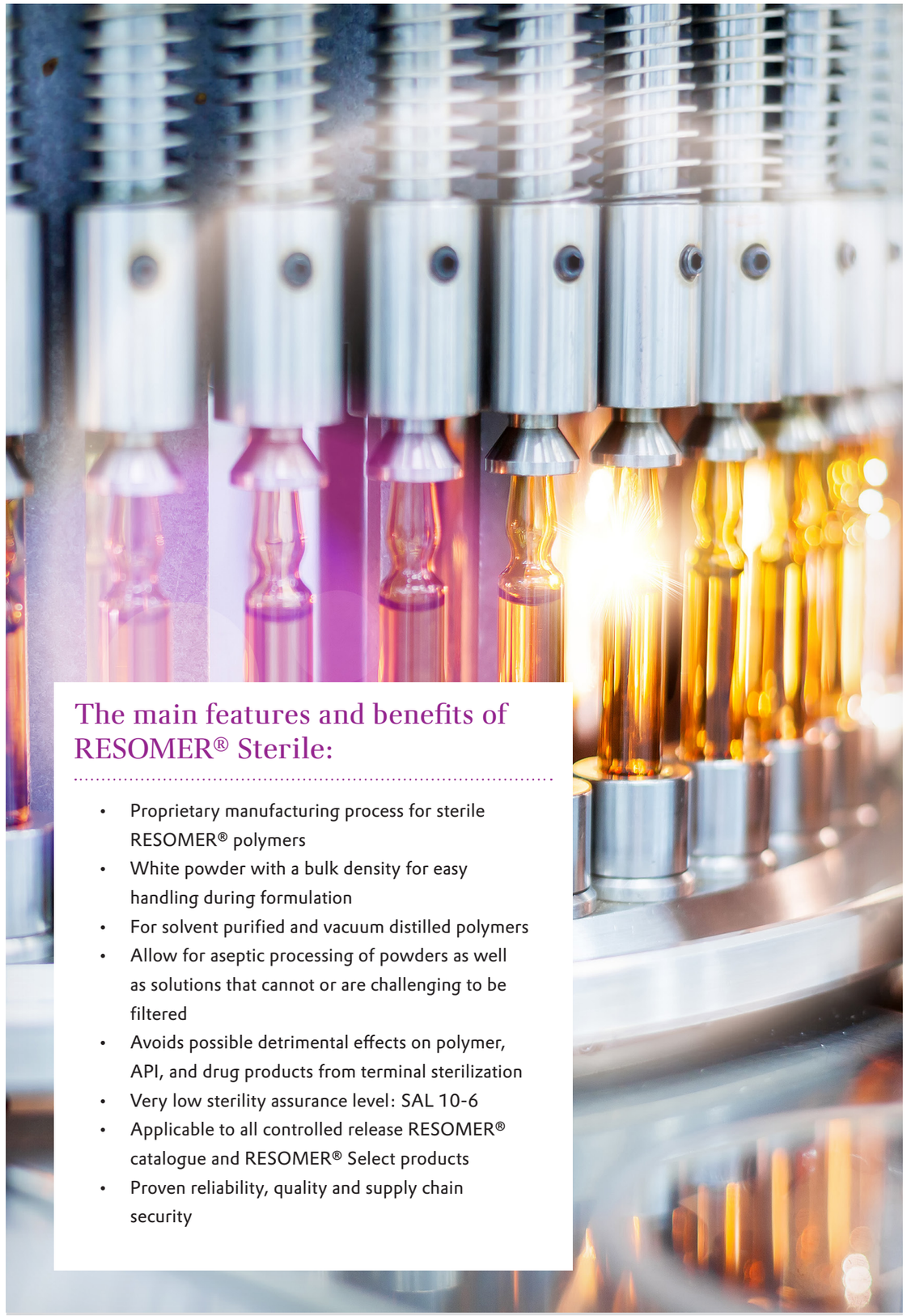
Ready. Sterile. Go.

Creating new manufacturing options and reduced steps for aseptic processing.

Resomer® Sterile

EVONIK
POWER TO CREATE



The main features and benefits of RESOMER® Sterile:

- Proprietary manufacturing process for sterile RESOMER® polymers
- White powder with a bulk density for easy handling during formulation
- For solvent purified and vacuum distilled polymers
- Allow for aseptic processing of powders as well as solutions that cannot or are challenging to be filtered
- Avoids possible detrimental effects on polymer, API, and drug products from terminal sterilization
- Very low sterility assurance level: SAL 10-6
- Applicable to all controlled release RESOMER® catalogue and RESOMER® Select products
- Proven reliability, quality and supply chain security

New options for the manufacturing of parenteral drugs

Improved process controls and streamlined steps for aseptic processing

RESOMER® Sterile is the first and only known sterile poly (lactic-co-glycolic) (PLGA) excipient for parenteral controlled release. Suitable for use with any RESOMER® standard or RESOMER® Select custom polymer for parenteral controlled release including solvent purified or vacuum distilled polymers. RESOMER® Sterile requires no further sterilization, creating significant flexibility to streamline process steps for the aseptic manufacturing of parenteral drug products. To minimize degradation and protect overall polymer integrity, the proprietary sterilization process delivers an extremely low sterility assurance level (SAL) of 10-6.

Highly flexible processing options

RESOMER® Sterile has been developed with improved process controls and streamlined steps for simplified aseptic processing to avoid potential detrimental effects on the polymer, sensitive APIs, or drug products that may otherwise occur during terminal sterilization. When used during electron-beam (e-beam) sterilization, which are often favored by pharmaceutical companies due to its relatively mild conditions, potential polymeric agglomeration, aggregation or fusion are avoided. To enable easy handling during formulation and to further enhance processing performance, it is supplied as a free flowing white powder or granular form that is tuned for optimized bulk density.

RESOMER® Sterile provides the flexibility to formulate drug products utilizing common powder or solution-based technologies during aseptic processing, including hot melt extrusion and 3D printing. To simplify downstream drug product manufacturing, it is ideal for use when sterile filtration is not possible, such as for highly viscous solutions or with special solvents that are not compatible with the filter membrane.

Sterility and Quality Assured

RESOMER® Sterile builds upon more than 30 years of excellence for biocompatibility and safety that has been established under the RESOMER® portfolio of excipients for parenteral controlled release. The manufacturing process for RESOMER® Sterile provides a robust and highly repeatable approach to optimize the sterilization of polymer excipients. These processes enable RESOMER® Select polymers to attain a best-in-class sterility assurance level (SAL) of 10-6. To further strengthen global supply security for use with parenteral drug products, RESOMER® and RESOMER® Select polymers can be manufactured at either of our two GMP manufacturing sites in the U.S. and Germany.

Suitable for use with catalog and custom RESOMER® polymers

RESOMER® Sterile versions are available on a made-to-order basis for use with any controlled release RESOMER® catalogue product or RESOMER® Select custom-made product. This broad, highly flexible product portfolio includes a range of amorphous Poly (D,L-lactide) and Poly (D,L-lactide-co-glycolide) polymers with a wide range of inherent viscosities (IV) and degradation times up to 18 months or more.

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