Exclusive Synthesis

A global CMO leader and preferred partner for API, HPAPI and intermediates with a broad portfolio of advanced technologies





MAKE EVONIK YOUR COMPETITIVE ADVANTAGE

Evonik is one of the world's leading specialty chemical companies. In 2018, our more than 36,000 employees produced sales of €15.0 billion and an operating result (EBITDA) of €2.6 billion. We hold market leading positions in 80% of our businesses, and are active across more than 100 countries and 175 sites globally.

The Evonik business line Health Care serves more than 1,000 pharmaceutical, medical device and nutraceutical customers, including 90 % of the world's top 50 life science companies.

For the exclusive synthesis of API, HPAPI and intermediates, we bring together unique core competencies across chemistry, biotechnology and engineering. Combined with a proud record of performance for quality and supply, and a broad portfolio of advanced technologies, we can address the specific needs of even the largest or most complex projects.



OUR CREDENTIALS TO SERVE AS YOUR CMO PARTNER

The global scale, technical expertise and flexibility to serve your long-term needs

3

One of the world's top 3 CMOs for API, and intermediates

 $170\,\mathrm{m}^3$

The world's largest HPAPI process developer and manufacturer $0.05 \, \mu g/m^3$

OEL for HPAPI

6

FDA-inspected sites in the U.S., EU and Asia

 -80° C

Cryogenic reactions

 $> 200 \,\mathrm{m}^3$

The world's largest cGMP capacity for cryogenic reactions

 $>4,000\,\mathrm{m}^3$

Total fermentation capacity

>20

Different enzymes applied in commercial scale

>25

Lab groups for chemical CMO development

>800

In-house engineers and chemists for investment projects

5

Consecutive years as an EcoVadis gold medal recipient for sustainability >50

Years of continuous processing expertise

BEST-IN-CLASS INDUSTRY CAPABILITIES



API AND INTERMEDIATES

- API (bulk, controlled) at any clinical or commercial scale
- From grams to thousands of tons per year
- Western-centered network of FDA-inspected production sites
- · Germany, USA, France, Slovakia and China
- Extensive particle design and API conjugation expertise



HIGH POTENCY AND ANTI-CANCER API

- The world's largest HPAPI CMO capacity from grams to tons
- 170 m³ total capacity, OEL down to 0.1µg/m³ (large-scale)
- cGMP high potent lab down to 0.05 μg/m³
- Support from process development to large-scale production
- · A broad range of reaction types covered
- The ability to produce up to 7 different API steps in parallel



CHEMISTRY AND BIOTECHNOLOGY

- The world's largest cryogenic capacity (-80 °C, 200 m³)
- Backward integration in catalysts
- · Large portfolio of homogeneous and heterogeneous catalysts
- Total fermentation capacity of more than 4,000 m³
- More than 20 different enzyme types already used in production



PROCESS ENGINEERING

- A proven track record of execution for major investment projects
- An in-house process engineering unit with more than 800 staff
- · Flexible project teams can be formed on demand
- A complete set of competencies such as particle technologies, fluid processing, bioprocess technology, supply chain management, CAPE and automation and reaction technology

A BROAD, FLEXIBLE PORTFOLIO OF ADVANCED TECH



THE WORLD'S LARGEST HPAPI CAPACITY FROM GRAMS TO TONS

- A total capacity of 170 m³ across two different sites in the U.S. and Europe
- Main site Tippecanoe Laboratories, Lafayette, IN, U.S.
 - From lab scale up to 8,000 l reactor volume
 - OEL down to 0.1 μg/m³ (large-scale)
- Small-scale production unit for ultra-HPAPI with an OEL down to 0.05 μg/m³



MORE THAN 2/3 OF EVONIK'S PRODUCTS MADE USING CONTINUOUS PROCESSES

- From process development to customized production, separation and work-up
- Established processes with a broad variety of reactor technologies including micro reactors, tube reactors, loop reactors, trickle-bed reactors plus CSTR and SMB
- Continuous separation and work-up technologies including distillation, extraction, crystallization and membranes
- New modular, continuous processing cGMP pilot plant (OEB 3) in Germany



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CUSTOM-TAILORED PEG SPECIALTIES FOR THE HIGHEST STANDARDS

- mPEG labs and a pilot plant in Germany for highly pure synthesis at the kg scale
- Commercial-scale cGMP production sites in Germany and the U.S.
- mPEG support from synthesis through to isolation, activation and conjugation
- Polydispersity (Mw/Mn): <1.05, Diol content (mPEG): <0.5 %, Average molecular weight: +/-2%



CARBOHYDRATE CHEMISTRY

A UNIQUE PORTFOLIO WITH DECADES OF SUGAR MODIFICATION EXPERTISE

- An expert in sugar derivatization, protective groups, and bioconversions
- Broad technology range for nucleoside API
- Fermentative production of oligosaccharides from kg to multi-ton scales



POLYMER CHEMISTRY EXCELLENCE APPLIED TO PHARMA APPLICATIONS

- A wide range of polymerization platforms including solution, suspension, emulsion, coordinative, radical, anionic, bulk and ring opening
- >60 years of expertise in polymer development, optimization and scale-up
- A network of U.S. and EU sites for the flexibility to support all polymer API process steps, with both batch and continuous process options available

NOLOGIES TO ADDRESS SPECIFIC PROJECT NEEDS

A GLOBAL LEADER FROM STRAIN DEVELOPMENT TO COMMERCIAL-SCALE

- 4000 m³ fermentation capacity across six sites in the EU, U.S. and Asia
- Flexible downstream processing pilot plant in Slovakia
- >30 years of expertise in microbial fermentation and biocatalytic technologies
- >25 commercial products based on fermentation
- Expertise across pharma, advanced food ingredients and nature-identical materials



THE NUMBER ONE WHITE BIOTECH IN EUROPE

- Full service from screening to biocatalyst supply and large-scale production
- Enzymatic chemistry with > 20 different enzymes applied at production scale
- A strong record in developing new enzyme platforms (bacteria, algae, fungi)
- More than 40 years of biotechnology expertise
- Development and scale-up of biocatalytic processes



FULL SERVICE FROM CATALYST DEVELOPMENT TO SCALE-UP AND PRODUCTION

- Large portfolio of heterogeneous and homogeneous catalysts
- > 30 years of process development expertise, with all key reactions covered
- Five global sites for catalytic reactions: Up to 25 bar; 80 °C 200 °C; 100 16.000 L; glass lined, steel or Hastelloy; with HPAPI options available



DECADES OF EXPERTISE IN ASYMMETRIC SYNTHESIS AND CHIRAL RESOLUTION

- A full portfolio from chiral pool synthesis to chemo-catalysis and biocatalysis
- Established production of > 100 chiral products including various amino acids
- A technology toolbox for chiral compounds including heterogeneous and homogeneous catalysts, reductive animation, and hydrazine reduction



THE WORLD'S LARGEST CGMP CAPACITY FOR CRYOGENIC REACTIONS

- A total capacity of 200 m³ across four different sites, reactions down to −80 °C
- Reactors from 500 L to 8 m³ reactors (glass lined and Hastelloy), up to 10 bar
- > 50 reactors with cryogenic capacities (batch or continuous processing)
- Organometallic reactions including Grignard available at three sites globally



A TRUSTED GLOBAL PRODUCTION NETWORK

TIPPECANOE, LAFAYETTE, INDIANA, US

- Four cGMP plants and pilot plant: 860 m³ capacity
- Total HPAPI capacity of $170 \, \text{m}^3$, down to $0.1 \, \mu\text{g/m}^3$ (large-scale)
- From lab scale up to 8,0001 reactor volume
- Extensive cryogenic capabilities (-80°C)
- Large-scale fermentation capacities (2,500 m³)

HANAU, GERMANY

- Multi-purpose cGMP site: 196 m³ capacity
- HPAPI-capable process / analytical labs $(0.05 \,\mu g/m^3)$
- Catalysis: Up to 25 bar, -80 °C 200 °C
- Dedicated PEG/mPEG kilolab
- · Modular continuous processing pilot plant

DOSSENHEIM, GERMANY

- Multi-purpose cGMP site: 180 m³ capacity
- Three plants for API and intermediates
- Equipped for controlled and organometallic substances, batch or continuous processing
- Catalysis: Up to 6 bar, -80 °C 200 °C

FERMAS, SLOVAKIA

- · Multi-purpose fermentation site
- · Amino acids, API building blocks, food ingredients
- Total fermentation volume of 1,150 m³
- DSP pilot plant including continuous sterilization

HAM, FRANCE

- Multi-purpose cGMP site: 65 m³ capacity
- Three plants with 34 vessels (0.25 6 m³)
- Large-scale ion chromatography
- · Purification of amino acids and derivatives

NANNING, CHINA

- Multi-purpose site: 70 m³ capacity
- Three cGMP sites and four amino acid plants
- 240 m³ fermentation and biotransformation capacity
- · Crystallization and ion exchange technology













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EVONIK NUTRITION & CARE GMBH

Health Care Business Line Exclusive Synthesis

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