

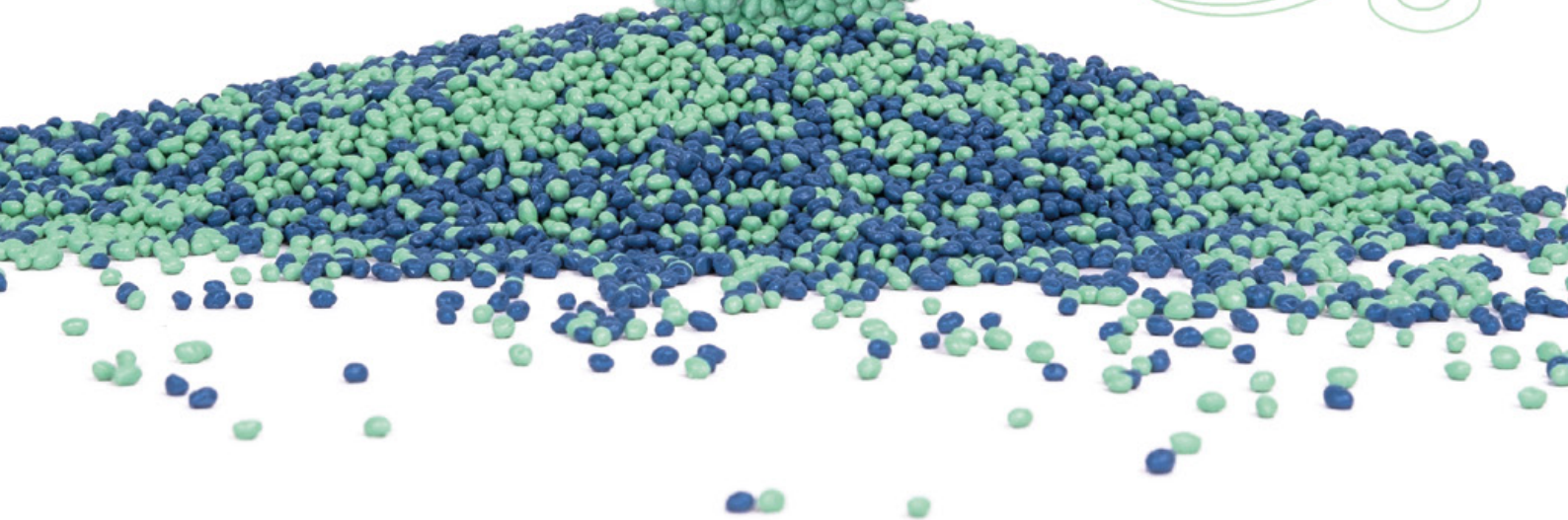
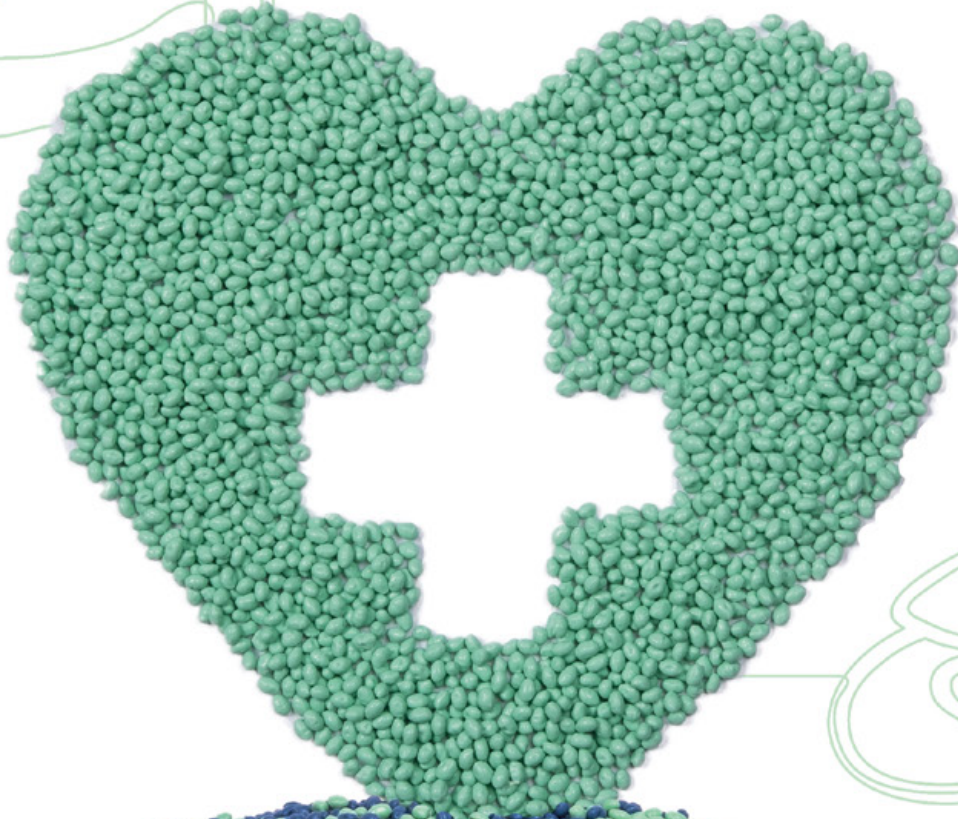


ELIX
POLYMERS

A member
Sinochem
International

High Performance ABS Products

for Medical
Applications





ELIX Polymers

is a leading manufacturer of ABS (Acrylonitrile-Butadiene-Styrene) resins and derivatives in Europe

Compromise



Certifications



Memberships



PlasticsEurope
Association of Plastics Manufacturers

feiQue
Innovative Plastics for a Sustainable Future

aeqt

Operating from its head office in Tarragona, Spain with sales support teams in all key markets around the world and as an Sinochem International member, the company is a specialist provider of tailor made solutions for high quality thermoplastics applications.

ELIX Polymers is an expert in ABS polymers, and it has the resources, the expertise and the experience to create value for its customers through highly individual solutions.

ELIX Polymers has strong technical expertise in product formulation and colour development and offers a range of high performance products that meet the stringent requirements of the Healthcare Industry. These include two USP class VI biocompatibility grades, which have registered device and drug master files for medical and food-contact applications. The company counts leading global pharmaceutical companies among its customers.

In addition, ELIX Polymers has ISO 9001, ISO 14001 and ISO 50001 certifications and fully underwrites the chemical industry's responsibilities.

ELIX Polymers' vision is to be the benchmark global leader in the specific thermoplastics market. As a customer-oriented company, ELIX Polymers offers a broad portfolio of products as well as personalised services. At the same time it is committed to addressing environmental sustainability and fostering the professional development of its employees.

To achieve this, the company has placed emphasis on continuous improvement, innovation, state-of-the-art technology, high quality products and production as well as safe and environmentally responsible processes.

The key factors are a high level of experience in the sales and technical marketing departments, as well as the professionals who make up the human capital of ELIX Polymers.

Portfolio Technical Data

Standard properties*	Test condition	Unit	Standard	ELIX ABS Grades	
				High Flow ELIX M203FC	High Stiffness ELIX M205FC
Melt Volume-Flow Rate	220°C/10kg	cm ³ /10min	ISO 1133	31	20
Flexural Modulus	2mm/min	MPa	ISO 178	2400	2600
Izod Notched Impact Strength	23°C	kJ/m ²	ISO 180-1A	15	15
Izod Notched Impact Strength	- 30°C	kJ/m ²	ISO 180-1A	7	7
Vicat	50N, 50°C/h	°C	ISO 306	99	98

*The figures should be regarded as guide values only and are not part of product specifications.

ELIX pre-colored ABS offer



- **Balance of good processability** (optimum flow) and mechanical properties.
- **Excellent surface quality** with high gloss finish and customised colours.
- **Full Compliance** with Medical Regulations.
- **Biocompatibility tests on ABS** with pigments are periodically conducted and passed according to ISO10993-1.
- **Sterilisation (gamma radiation, ethylenoxide)** and excellent mechanical property retention under typical sterilisation doses of 25-50 KGy.
- **Hydrolytic stability** over time at elevated temperatures.
- **Resistance** to a broad range of chemicals and body fluids.
- **Tough and durable.**

Applications



Infusion Systems

- Connectors
- Caps
- Spikes
- Slide Clamps
- Roller Clamps



Respiratory Devices

- DPI (Dry Powder Inhaler)
- Inhaler
- MDI (Metered Dose Inhaler)



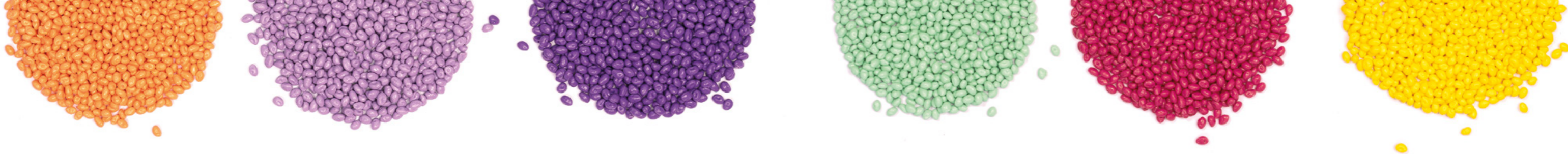
Auto Injection Devices

- Lancing Devices
- Insulin Pen
- Auto Injection Pens



Others

- Housing for Medical Devices
- Closed System
- Transfer Device



ELIX commitment to the Medical Industry

Quality Assurance of Raw Materials & Intermediates

Dedicated quality management team

- Special selection of suppliers, raw materials & intermediates with homologation process.
- Specific testing on all raw materials, intermediates and final products.
- Close cooperation with customers to meet exacting quality results.



Product formulations / sample storage

No-change agreement of up to 3 years* Extended sample storage for 3 years

* In connection with long-term supply agreement

Product stewardship



Selection of FDA approved pigments, additives and concentrations



Formulation optimisation complying with actual legislation and biocompatibility ranges



Surveillance on changing medical regulatory framework

Technical service

- Technical support all along the value chain (processing, design, production).
- Long-term experience.
- Troubleshooting online and in-house on customer premises.

Colour Development

Special selection and listing of FDA and EU-FC approved pigments and additives

Database of more than 120 matched colours

Recognised benchmark in the medical industry

ELIX special developments

medical ABS grades optimised for laser making

Optimised formulation that captures the laser energy more efficiently, enhances laser markability and assures medical compliance.



Optimised formulation for laser marking with registered DMF.



Biocompatibility and FDA & EU-FC approved selected pigments & additives.

Regulatory compliance

	ELIX M203FC	ELIX M205FC
General		
DMF - Type III	25288	25284
Letter of Authorisation*	✓	✓
Pharmacopoeia		
Europe		
EU, 7th Edition Chap 3.2.2.	✓	✓
"Plastics Containers and Closures"		
US		
USP Class VI	✓	✓
Up to 30 days human contact duration		
Biocompatibility - ISO 10993-1		
Biocompatibility Tests for Cytotoxicity, in Vitro Hemocompatibility etc.	✓	✓
Food Contact		
EU Regulation no. 10/2011	✓	✓
FDA regulation 21CFR §	✓	✓
Germany, BfR - Recommendations	✓	✓
Others		
REACH compliant products	✓	✓
RoHS 2011/65/EU compliant products	✓	✓
BSE/TSE absence of risk	✓	✓
Non-use of endocrine effective substances	✓	✓

* Upon request

Note: This information and our technical advices are given in good faith. Biocompatibility-tests mentioned are not part of our continuous quality control. Our advice does not release the end article manufacturer from the obligation to check its validity and to test our products as to their suitability for the intended processes and uses.

E-LOOP

Let's close the loop

Further documents are available on **ELIX Polymers website:**

E-LOOP covers all Circular Economy initiatives in terms of product, design and service.

Circular Plastics & Responsible Innovation are the strategic programmes of ELIX Sustainable Portfolio Solutions.

Circular Economy



Let's close the loop!

ELIX Polymers has developed mechanical and chemical recycled products with equivalent material properties to prime material.

Depending on the application and the part requirements we support you to choose the right material.

In particular, chemical recycling is aimed at applications such as medical and healthcare, where it is difficult to implement recycled materials while ensuring full regulatory compliance.

ELIX medical ABS grades with chemical recycled content are 100% chemically identical to standard ELIX medical ABS produced from fossile feedstocks and offer the same DMF, biocompatibility results and regulatory compliance.

Sustainability report



Responsible innovation

ELIX Sustainable Goal I. Promote a circular plastics economy system.

ELIX Sustainable Goal IV. Contribute to reducing biodiversity loss.

- Improve the sustainability of ELIX materials.
- Promote the design of reusable and recyclable products.



Circular plastics

ELIX Sustainable Goal I. Promote a circular plastics economy system.

- Recover and reuse or recycle discharged ABS and blend components and materials.
- Use raw materials from renewable or recycled sources.
- Strengthen collaboration along the value chain to create new circular business models.
- Improve customer engagement and logistics to close material loops.
- Improve transparency and traceability of flows.



Technical Resources

Further documents are available on **ELIX Polymers website:**

Technical papers



ELIX Injection Moulding Guidelines



ELIX Paintability Guidelines



ELIX Vicat Guidelines

Solutions portfolio



TDS



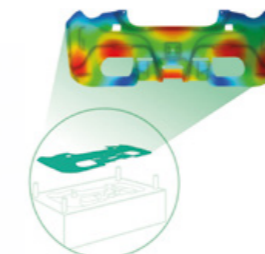
ELIX ABS medical grades



ELIX pre-coloured ABS solutions



Chemical resistance evaluation of ELIX ABS grades



ELIX files for Moldflow and Moldex3D simulations

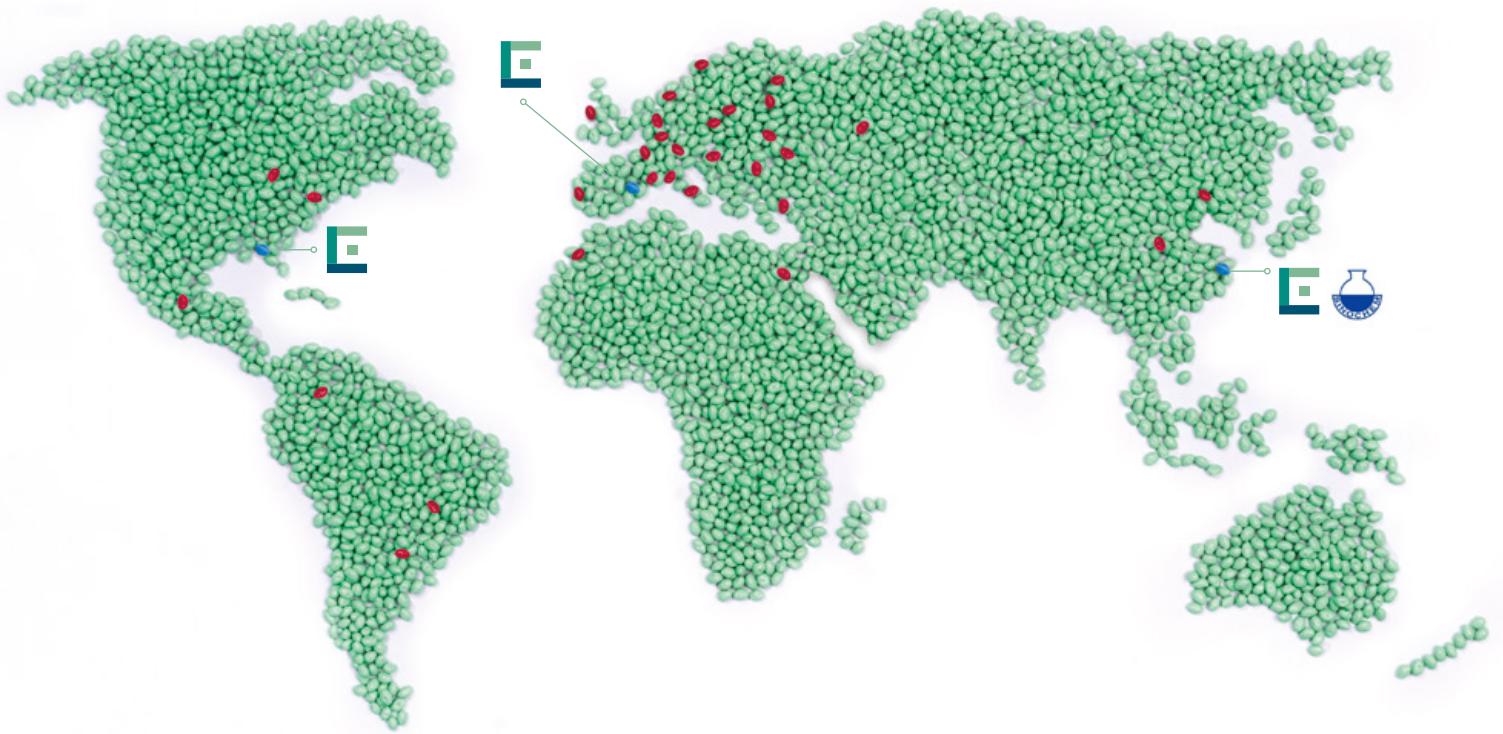


ELIX ABS CC products for special requirements on safety of use



Improvement in aesthetic laser marking





ABS Manufacturer

*Global presence, covered by
extensive ELIX Polymers' sales
force, distributors and agents*



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