

Manufactured for Being Human

Soft-touch Plastics
for Medical Applications



Highest Standards for Our Most Human Products

Our TPEs for the medical market offer quality,
safety, and reliability

One might think that plastics is not the most emotional business. But we think otherwise. We look beyond the mechanics of it all and see how our materials shape people's lives. This figures most prominently in the medical sector, where Trinseo compounds are intrinsic to the medical devices that improve health and wellness and increase liveability.

We look back on nearly three decades of supporting the medical devices market with rigid plastics of outstanding quality. Trinseo is now also offering a portfolio of thermoplastic elastomers (TPEs) for the medical market, thereby addressing a growing demand for applications requiring soft-touch materials for ergonomics, functionality, safety, and aesthetics.

Our materials are available in a broad range of hardness, melt flows, and finishes for excellent processability of injection molded applications and they are suitable for overmolding. But most of all, they are suitable for what makes us human.

Being Human.

Soft-touch Plastics for Medical Applications

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Trinseo Fast Facts



Global Operating Center Office Plastics & Feedstocks Latex Binders Synthetic Rubber

About Trinseo

Trinseo is a technology leader and innovator in performance plastics solutions. Our manufacturing, Research & Development (R&D), and testing facilities located strategically across the globe, allow us to collaborate, develop and manufacture seamlessly across regions.

For the medical devices industry, we offer a broad portfolio of advanced resins to meet the shape, design, aesthetic, and performance requirements of medical applications. All of our manufacturing facilities adhere to stringent processes. This allows us to offer materials with worldwide equivalency, consistency of quality, and assurance of supply. We hold ISO 9001, 14001, 16949 and 13485 certifications.

Trinseo's emphasis is on ensuring the highest quality materials as the foundation for its compounded products. This not only applies to the polycarbonate, ABS, and polystyrene resins we use but to our raw materials as well. By using our best sources for resins, managed under tightly controlled conditions, we are able to deliver products consistently, predictably, and sustainably across the globe.

Global Resources, Local Production

Trinseo delivers an unmatched combination of global reach, operational excellence, expertise, leading intellectual property, world-scale assets, and global R&D presence.

\$3.8 B

REVENUE IN 2019



11

R&D FACILITIES GLOBALLY



2,700

EMPLOYEES IN 25 COUNTRIES



17

MANUFACTURING SITES GLOBALLY



Medical Grades with a Human Touch

Medicine is more than just a science based on research and years of innovation. Medicine is in fact the most human and humanitarian thing. It is about caring for each other. Healing one another. And making life more valuable.

These considerations drive us day in, day out to focus our efforts even more on what it means to be human.

Soft-touch Plastics for Medical Applications


Trinseo offers two TPE chemicals for the medical market: Styrene Ethylene Butylene Styrene (SEBS) and Styrene Butadiene Copolymer (SBC). In addition, a family of skin-contact TPE grades is available for appropriate applications:

MEGOL™ MED
TPS-SEBS Compounds

RAPLAN™ MED
TPS-SBC Compounds


MEGOL™ SK
TPS-SEBS Compounds

Our medical TPE products and product families are optimized for a variety of medical soft-touch plastic applications:




Single- and multiple-use devices

Stopcocks, trocars, luer locks, syringes, respiratory devices, and handheld medical surgical instruments




Medical wearables

Personal health monitors, fitness and lifestyle trackers



Equipment housings

Powered and non-powered housings and enclosures for a variety of diagnostic equipment



Drug delivery systems

Auto injectors, insulin pens, inhalers, prefilled syringes

Food contact, skin contact compliance and biocompatibility testing:

Food Contact Grades	Skin Contact grades (SK)	Medical grades (MED)
Regional food contact compliance	cGMP compliance	Medical NOC policy (2 years)
	ISO 10993 tests: <ul style="list-style-type: none">→ ISO 10993-5→ ISO 10993-10→ USP 661 Physicochemical study (aqueous and non-aqueous (isopropyl alcohol – IPA))	ISO 10993 tests: <ul style="list-style-type: none">→ ISO 10993-4→ ISO 10993-5→ ISO 10993-6→ ISO 10993-10→ ISO 10993-11→ USP 661 Physicochemical study (aqueous and non-aqueous (isopropyl alcohol – IPA))

High-quality Medical TPE Grades for Sensitive Applications

Our medical TPS-SEBS and TPS-SBC compounds provide optimal quality, safety, and reliability for sensitive medical applications requiring utmost care.

Trinseo offers a comprehensive Management of Change process that includes lot traceability, a formulation lock, Notification of Change, extended record and sample retention. The medical-grade products are manufactured with a high level of attention to quality and compliance requirements and we ensure stable supply in a timely manner. Our medical grades provide:

- Manufacturing and/or final compounding according to cGMP
- Full battery of ISO 10993 biocompatibility testing (Parts 4, 5, 6, 10 & 11)
- USP 661 Physicochemical study (aqueous and non-aqueous (isopropyl alcohol – IPA))
- Medical Notification of Change policy – formulation “lock”/notification of 2 years (24 months)
- Inclusion in Master Access Files (MAF) and/or Drug Master Files (DMF)*

*Available for some products

MEGOL™ MED TPS-SEBS Compounds

MEGOL™ MED AD Series, MEGOL™ MED IP Series, and MEGOL™ MED IF Series

Base Polymer	Features	Technical Details	Processing Methods	Potential
Styrene Ethylene Butylene Styrene (SEBS)	Elastic property with the softness of rubber	Good hardness range: 25 ShA – 80 ShA	Injection molding	Soft closure caps
	Translucent or opaque	Excellent UV and aging resistance	Overmolding	Tracheotomy patches
	Very strong adhesion on polar (PC, ABS, PC/ABS) and non-polar (PP) substrates	Chemical resistance to cleansing agents used in the medical sector		Caps & closures
	Can be colored	Sterilizable Recyclable		Surgical tool handles



Focused on what medicine is really about. People.

RAPLAN™ MED TPS-SBC Compounds

RAPLAN™ MED

Base Polymer	Features	Technical Details	Processing Methods	Potential
Styrene Butadiene Copolymer (SBC)	Highly transparent	Hardness: 52 ShD	Injection molding	Infusion drip chambers
	Non-halogenated material (no chlorine, bromine, iodine, fluorine)	Chemical resistance to cleansing agents used in the medical sector		
	Suitable for solvent welding	Sterilizable		
	Excellent substitute for PVC	Recyclable		
	Can be colored/tinted			

Meeting technical standards. Clients' needs. And the daily bathroom routine.



Skin-contact TPE Grades for High Quality Standards

Trinseo skin-contact TPE grades are manufactured with a high level of attention to both quality standards and compliance requirements as well as stability of supply. Our skin-contact grades are suitable for applications in which there is no or non-invasive contact with the patient. They offer:

- ISO 10993 biocompatibility testing (Parts 5 & 10)
- USP 661 Physicochemical study (aqueous and non-aqueous (isopropyl alcohol – IPA))
- Trinseo standard Notification of Change policy for medical products

MEGOL™ SK TPS-SEBS Compounds

MEGOL™ SK Series

Base Polymer	Features	Technical Details	Processing Methods	Potential
Styrene Ethylene Butylene Styrene (SEBS)	Elastic property with the softness of rubber	Good hardness range: 20 ShA – 80 ShA	Injection molding	Wearables
	Translucent or opaque	Excellent UV and aging resistance	Overmolding	Monitors
	Very strong adhesion on non-polar (PP) substrates	Chemical resistance to cleansing agents used in medical sectors		Oxygen masks
	Can be colored	Sterilizable		Nebulizers
		Recyclable		Surgical tool handles

An Extra Layer of User-friendly Quality

Overmolding can be found in a wide range of healthcare applications ranging from surgical and dental instruments to wheel chair grips, from drug delivery devices to medical wearables. The demand for the overmolding process is being driven by several trends – a move toward home healthcare, growth in self-administered treatments, and an overall aging population.*

* The U.S. Food and Drug Administration (FDA) may have contributed to the interest in overmolding. The FDA issued a guidance document called “Applying Human Factors and Usability Engineering to Medical Devices” (revised February 2016). The intent of this report is to encourage manufacturers to make sure their devices can be used safely, without causing harm or lessening the effectiveness of treatment.

VDI 2019 and Our Specialized Overmolding Center (SOC)

Trinseo has a long heritage in performance plastics in the development of rigid plastic materials. Since the acquisition of API in 2017, the company has gained unique expertise in both the formulation technology and compounding processes of TPE solutions. This expertise expands the synergies between our rigid- and soft-touch product portfolios.

At our manufacturing site in Mussolente, Italy, we established the Specialized Overmolding Center (SOC) for research. The SOC is equipped with state-of-the-art laboratory equipment enabling our experts to measure the adhesion between soft and rigid components in accordance with the VDI 2019 standard, which defines bond strength.

Trinseo is an active member of the committee that was specifically formed to define a common testing protocol and documentation requirements used for determining the bonding strength between a soft component and a rigid substrate. It enables us to determine the adhesion in relation to the main injection parameters:

- Material temperature
- Mold temperature
- Injection speed
- Injection pressure/post pressure

The functional, visual, and tactile properties of rigid plastics applications can significantly benefit from being overmolded with adhesion-modified TPEs. Our soft-touch solutions for overmolding offer design flexibility and optimized appearance. They also enable lighter weight and can enhance the durability of a wide range of multicomponent applications.

		MEGOL™ MED AD Series						MEGOL™ MED IP Series			MEGOL™ MED IF Series		
		Adhesion on polar substrates						Adhesion on polyolefine			Adhesion on polyolefine		
Hardness	ASTM D2240	ShA (15")	30	45	55	65	80	25	50	80	25	55	80
Hardness	ASTM D2240	ShD (3")	-	-	-	-	25	-	-	-	-	-	-
Polyolefine (PP OMO polymer)	VDI2019	N/mm	-	-	-	-	-	3.0 D	7.0 D	9.0 D	2.0 D	4.5 D	6.0 D
MAGNUM™ 8391 MED HM88010057	VDI2019	N/mm	1.5 A	-	3.0 A	-	4.5 A	-	-	-	-	-	-
EMERGE™ PC/ABS 7700 EU	VDI2019	N/mm	2.0 A	-	4.0 A	-	6.0 A	-	-	-	-	-	-
CALIBRE™ 5101 FC850122	VDI2019	N/mm	2.0 A	-	4.2 A	-	6.0 A	-	-	-	-	-	-
CALIBRE™ 2061 FC850122	VDI2019	N/mm	2.1 A	-	4.1 A	-	5.8 A	-	-	-	-	-	-
CALIBRE™ 5201 FC850122	VDI2019	N/mm	2.3 A	-	3.8 A	-	6.0 A	-	-	-	-	-	-

Medical and Skin-contact TPE Classification Data

MEGOL™ MED Series

MEGOL™ MED IP Series					
Adhesion on polyolefine					
Appearance	Translucent				
Biocompatibility Testing	ISO 10993 part 4, 5, 6, 10 & 11, physicochemicals				
Sterilization - Steam Autoclave	YES				
Sterilization - Gamma (25 kGy – 50 kGy)	YES				
Sterilization - Ethylene Oxide	YES				
Hardness	ASTM D2240	ShA (15")	25	50	80
Density	ASTM D792	g/cc	0.89	0.89	0.89
MFI (230°C – 21,18N)	ASTM D1238	g/10'			
MFI (190°C – 49,05N)	ASTM D1238	g/10'	25	35	25
Tensile strength	ASTM D638	MPa	6	8	13
Elongation at break	ASTM D638	%	750	750	800
Tear strength (type C)	ASTM D624	kN/m	14	23	44

MEGOL™ SK Series

MEGOL™ SK IP Series						MEGOL™ SK IF Series		
Adhesion on polyolefine						Adhesion on polyolefine		
Appearance	Translucent					Opaque		
Biocompatibility Testing	ISO 10993 part 5, 10, physicochemicals					ISO 10993 part 5, 10, physicochemicals		
Sterilization - Steam Autoclave	YES					YES		
Sterilization - Gamma (25 kGy – 50 kGy)	YES					YES		
Sterilization - Ethylene Oxide	YES					YES		
Hardness	ASTM D2240	ShA (15")	20	50	80	20	60	85
Density	ASTM D792	g/cc	0.89	0.89	0.89	1.19	1.19	1.19
MFI (190°C – 49,05N)	ASTM D638	MPa	25	35	25	20	20	16
Tensile strength	ASTM D638	%	5.5	7.5	12	3.5	7	10
Elongation at break	ASTM D624	kN/m	800	750	750	750	750	700
Tear strength (type C)	ASTM D624	kN/m	15	23	44	13	26	40

MEGOL™ MED IF Series			MEGOL™ MED AD Series				
Adhesion on polyolefine			Adhesion on polar substrates				
Opaque			Opaque				
ISO 10993 part 4, 5, 6, 10 & 11, physicochemicals			ISO 10993 part 4, 5, 6, 10 & 11, physicochemicals				
YES			YES				
YES			YES				
YES			YES				
25	55	80	30	45	55	65	80
1.19	1.19	1.19	1	1.01	1.01	1.02	1.05
			21		23	15	
20	20	16	45	14			
4.5	6.5	9	3.2	4.4	4.4	5.6	8.3
800	750	700	825	723	751	786	806
14	22	36	16	23	28	31	35

RAPLAN™ MED

RAPLAN™ MED 52 D			
Appearance	Transparent		
Biocompatibility Testing	ISO 10993 part 4, 5, 6, 10 & 11, physicochemicals		
Sterilization - Steam Autoclave	YES		
Sterilization - Gamma (25 kGy – 50 kGy)	YES		
Sterilization - Ethylene Oxide	YES		
Hardness	ASTM D2240	ShD (15")	52
Density	ASTM D792	g/cc	1
MFI (190°C – 49,05N)	ASTM D638	MPa	10
Tensile strength	ASTM D638	%	15
Elongation at break	ASTM D624	kN/m	300
Tear strength (type C)	ASTM D624	kN/m	88

Soft-touch Plastics Product Range

With the acquisition of API Applicazioni Plastiche Industriali S.p.A. in Mussolente, Italy, we expanded our products portfolio to include soft-touch polymers. In addition to our well-known rigid plastics, we also manufacture and provide a broad range of customized TPE and TPU products and EVA-based compounds.

Trinseo's soft-touch plastics – suitable for a wide range of applications in all common markets – are polymers or polymeric compounds that possess both thermoplastic and elastomeric properties at working temperatures. You can benefit from successful long-term experience in powering applications with soft-touch polymer materials and technological expertise providing flexible solutions for a broad range of medical devices.

Styrenic block copolymers (TPS)

MEGOL™ TPS-SEBS Compounds

The MEGOL™ family of TPE compounds offers the ideal combination of the elasticity and look and feel of rubber in combination with the low processing costs of thermoplastics. MEGOL™ TPS-SEBS Compounds provide a wide range of optimum cold and hot elasticity, UV and age resistance, low emissions and low fogging, a large processing window, great looking, excellent soft-touch properties, and a good compression set.

RAPLAN™ TPS-SBS Compounds

RAPLAN™ are SBS (styrene butadiene styrene) elastomer-based thermoplastic compounds. The elastomer phase provides the elastic property and the softness characteristic of rubber to the compounds. RAPLAN™ TPS materials are an ideal substitute for PVC when halogen-free products are required. The use of specific additives improves this feature. Ideal for overmolding on polystyrene, RAPLAN™ is also suitable for injection-molding, footwear, and for extrusion.

Olefinic thermoplastic elastomers (TPO)

APIGO™ TPO Compounds

APIGO™ materials consist of polyolefin-based compounds modified with elastomers and were created to meet market demands for light products that are highly resistant to low temperatures. APIGO™ TPOs are alternatives to flexible PVC wherever halogen-free materials are required.

NEOGOL™ OBC Compounds

NEOGOL™ OBC are olefin block copolymer-based thermoplastic compounds (TPO) on a "styrene-free" chemical structure, offering excellent resistance to UV rays and aging. NEOGOL™ OBC's exceptional processability ensures high aesthetic quality with large surface areas and at very reduced thicknesses. Above all suited to injection molding, they may be supplied in grades suitable for contact with food. An excellent substitute for PVC in the production of halogen-free articles, they provide a valid alternative to conventional TPEs in applications not requiring specific physical-mechanical properties.

Thermoplastic rubber vulcanizates (TPV)

TIVILON™ TPV Compounds

TIVILON™ is a family of TPE products based on dynamically Vulcanized Thermoplastic Elastomers (TPVs). It provides high elasticity at low and high temperatures, excellent compression set, UV resistance and high melt flow. TIVILON™ is particularly well-suited to bonding with other materials for co-molding and co-extrusion with polyolefins and their compounds.

Copolyester thermoplastic elastomers (TPC)

API L™ TPC Compounds

API L™ is a block polyether-polyester thermoplastic elastomer (TPC), ideal for components that require maximum fatigue resistance, elasticity, toughness (even at low temperatures), tear resistance, and chemical resistance.

Urethane thermoplastic elastomers (TPU)

APILON™ 52 TPU Polymers and Compounds

APILON™ 52 is a line of thermoplastic polyurethanes (TPU) with excellent mechanical properties, high elasticity and superior resistance to low temperatures. APILON™ TPUs are very durable and suitable for applications where a high level of resistance to abrasion, oils, and fats is necessary and can be customized to suit specific application requirements.

APILON™ 52C TPU Polymers and Compounds

APILON™ 52 C are urethane-based thermoplastic elastomers (TPU) developed for the production of synthetic fabrics by dissolving them in solvents and then subsequent coagulation. They stand out for their excellent physical-mechanical characteristics that provide unique toughness, abrasion resistance, flexibility and elasticity at a range of working temperatures. APILON™ 52 C includes soft and rigid grades (ester-, ether-, and hybrid ester-ether-based), special polycarbonate-based grades, and other innovative grades that are the result of polymer alloys.

EVA-based compounds

APIFIVE™ EVA-based Compounds

APIFIVE™ are EVA-based expandable and cross-linkable compounds, modified with elastomers to enhance their softness, opacity, and soft-touch whilst maintaining optimum aesthetic appeal. APIFIVE™ grades are available in different expansion grades and in a broad range of colors. All these products are characterized by their low density enabling lightweight applications.

APIZERO™ EVA-based Compounds

APIZERO™ products are crosslinkable and expandable products based on EVA (ethyl-vinyl acetate) for injection molding. APIZERO™ grades were developed to meet the market needs for materials to produce light and sustainable applications. It can successfully compete with conventional products such as two-component polyurethane.

Bioplastics

APINAT™ BIO

Biodegradable TPC Compounds

APINAT™ BIO is a range of biodegradable thermoplastic bioplastics (TPE-E or TPC) that conform to the EN 13432 standard. These compounds include soft and rigid grades, special food-contact-approved grades and the “OK compost” certification of compostability.

APINAT™ BIO is the only soft biodegradable bioplastic available on the market with an international patent. These bioplastics enable the production of rigid-soft applications through overmolding that are totally biodegradable.

APINAT™ F BIO

Biodegradable TPC Compounds

APINAT™ F BIO is a range of biodegradable thermo-plastic bioplastics that are compostable in accordance with the standard EN 13432. These compounds are suitable for flexible packaging (such as shopping bags) and mulching.

They are easily processible with standard blow extrusion equipment. APINAT™ F BIO materials include special food-contact-approved grades with the “OK compost” certification of compostability.

APIGO™ BIO

Bio-based TPO Compounds

APIGO™ BIO are olefin-based thermoplastic bioplastics (TPE-O or TPO) containing raw materials from renewable resources. They guarantee the same physical-mechanical properties and the same processability as traditional fossil-based TPE-O. The APIGO™ BIO materials include soft and rigid grades, special food-contact-approved grades, and they have biocompatibility certification.

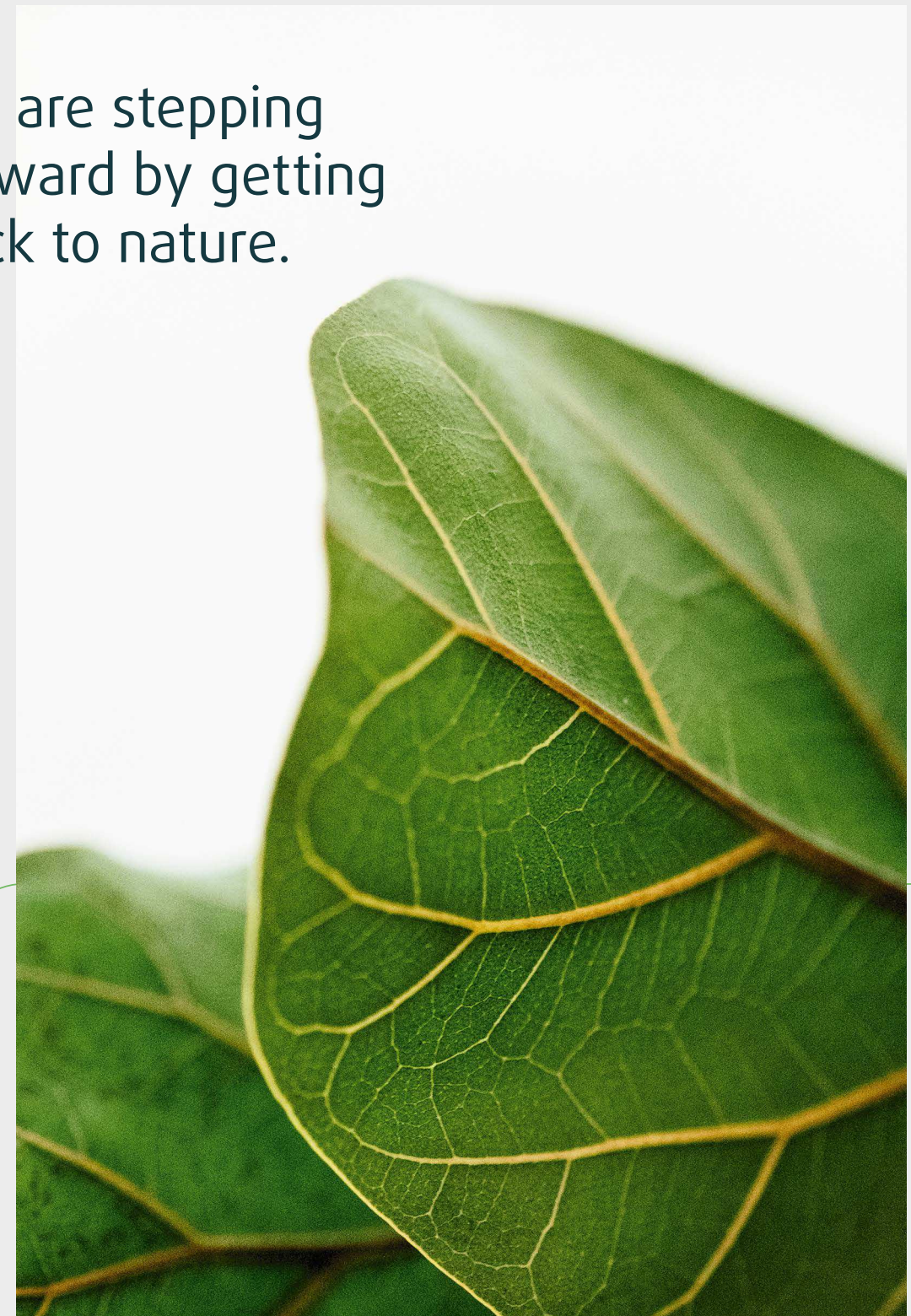
APILON™ 52 BIO

Bio-based TPU Polymers and Compounds

APILON™ 52 BIO are urethane-based thermoplastic bioplastics (TPE-U or TPU) containing raw materials from renewable sources offering the same performance as traditional fossil-based TPE-U. The family of APILON™ 52 BIO materials includes soft and rigid grades (ester, ether, ester-ether-based). We also offer special haptic compounds that give the product rubbery and matt properties.

APIGO™ BIO and APILON™ 52 BIO offer significant environmental benefits by reducing emissions of greenhouse gases (e.g. CO₂) and saving fossil-based resources for future generations.

We are stepping forward by getting back to nature.



Membership

Trinseo is a member of the European Bioplastics association.

europa
bioplastics

www.european-bioplastics.org

The principles of Responsible Care® and sustainability influence the production of printed literature for Trinseo S.A. and its affiliated companies. As a contribution towards the protection of our environments, Trinseo's printed literature is produced in small quantities and on paper containing recovered/post-consumer fiber and using 100 percent soy-based ink whenever possible.

Product Stewardship

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

Customer Notice

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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