

**Technical Plastics and Engineering Excellence
in Pharmacy, Medical and Food Technology**



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Use of plastics in medical, food technology and pharmaceutical applications



ENSINGER develops and produces semi-finished products, components and profiles from thermoplastics, which are particularly well suited for the very high demands of medical technology.

ENSINGER high temperature plastics possess properties which enable them to meet specific hygiene standards.

- | Biocompatibility and FDA conformity provide the required physiological safety
- | Very high resistance to
 - Cleaning agents, disinfectants and many solvents
 - Common sterilisation processes using super-heated steam, ethylene oxide, hot air or gamma rays
- | Suitable electrical properties:
Good electrical insulation in high-frequency surgery
- | Precision and stability of the finished parts and components

The combination of these properties contributes to the long useful life of quality instruments that are used frequently, thus reducing the costs of procurement and disposal.

ENSINGER qualifies in medical technology

The qualification and documentation requirements of products and their approvals are very high, especially in medical technology. ENSINGER is approved to DIN EN ISO 13485 : 2003 standard for compounding, semi-finished products, profiles, injection moulding and machining production departments.

In this way, ENSINGER satisfies a special need by providing complete product traceability. Pre-tested materials alleviate the approval of the customer's own medical device products.

Special materials from ENSINGER conform to the requirements of the Food and Drug Administration and equivalent European standards.

Materials compliant to United States Pharmacopoeia (USP class VI) and to ISO 10993 are also available.

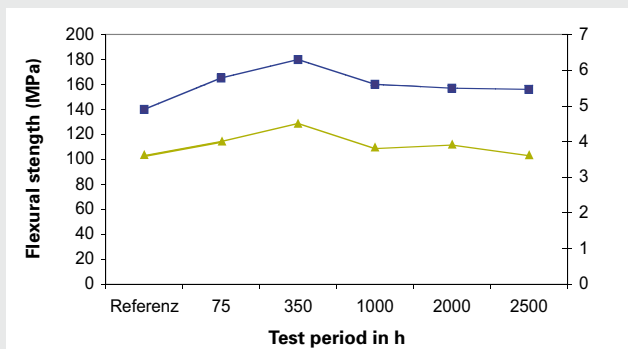


TECAPEEK CLASSIX™ (PEEK)



TECAPEEK CLASSIX™ is a high performance biocompatible thermoplastic, which was developed for applications in dentistry and medical technology with blood and tissue contact up to 30 days.

- | For medical applications with tissue contact up to 30 days
- | FDA conformity and biocompatibility testing according to USP. Raw material and semi-finished goods are tested batchwise for cytotoxicity according to ISO 10993.
- | Extreme resistance to hydrolysis, even at high temperatures
- | Can be frequently and repeatedly sterilised with conventional methods (hot steam, gamma radiation, plasma and ethylene oxide) without interfering with the mechanical properties
- | Particularly good combination of strength, rigidity, toughness and hardness
- | Excellent abrasion and impact strength
- | Standard colour is currently creamy-white, further colours and modifications upon request (e.g. visibility in x-rays, s. page 12)



Extremely high resistance to hydrolysis: Mechanical properties of **TECAPEEK CLASSIX™** over different periods of time (hot steam at 200 °C and 14 bar compression).



TECAPEEK CLASSIX™. Dental healing caps can stay in the body for up to 30 days.

Safety in many different areas of medical technology



ENSINGER MT plastics are made of FDA-approved raw materials. They are also tested for their biocompatibility on semi-finished products at regular intervals. These particular characteristics and the specific sterilisation stability predetermine their use in the area of medical and pharmaceutical technology.

Our project partners profit from the vast experience that ENSINGER possesses in different areas of medical technology. ENSINGER finds the optimal solution for each defined application by detailed consideration of every special requirement. This application oriented project management approach includes.

Diagnostics

With their transparency and resistance to electromagnetic waves, ENSINGER plastics are tried and tested for use in x-ray machines, CT scanners, blood analysers and imaging processes.

Surgery

ENSINGER's high performance plastics are used in many surgical instruments, e.g. surgical scissors, forceps, clamps, endoscopes, hand grips, fixation rods or for temporary implants.

Dentistry

Plastics for instruments used to remove plaque or to cure filling materials have to meet high requirements with regards to repeated sterilisation. ENSINGER plastics provide the best biocompatibility for rinsing handpieces used for water and air.

Therapy

High performance thermoplastics guarantee the correct functioning of respirators and medium diffusion units in dialysis machines.

Pharmaceuticals

Drug delivery systems are becoming more complex and more patient friendly. ENSINGER plastics play a significant role in this important market.



TECAPEEK MT (PEEK)

- | Very high chemical resistance
- | Excellent resistance to common methods of sterilisation
- | Good radiation resistance
- | Low susceptibility to stress cracking
- | High dimensional stability and easy to machine
- | Excellent tribological properties
- | Good electrical insulation, even at high voltage

TECAPEEK CF 30 MT (PEEK)

- | Very high stiffness and creep resistance
- | Excellent heat distortion resistance
- | Outstanding chemical resistance
- | Extremely wear resistant
- | Excellent dimensional stability
- | Physiologically safe
- | Good sterilisation resistance

TECATRON MT (PPS)

- | Very high chemical resistance
- | Good radiation resistance
- | Very good thermal and mechanical properties
- | Sustained use at temperatures up to 230 °C
- | Very hard and rigid
- | Very stable dimensionally with low susceptibility to creep

TECASON P MT (PPSU)

- | Excellent resistance to common methods of sterilisation
- | High thermal stability: long term service temperature 170 °C
- | Very tough, hard and rigid
- | Very good insulation
- | Low water absorption
- | Modification for X-ray visibility available (s. page 12)



TECAPEEK MT. Guide assembly for tube fixture in computer tomograph from SIEMENS.



TECAPEEK MT / TECAPEEK PVX. Joint for MRT from INNOMEDIC.



TECAPEEK MT. MD-key for KAVO Dental.

TECAPEI MT (PEI)

- | Translucent
- | Transparent to high-frequency electromagnetic waves
- | Good thermal and mechanical properties. Sustained use at temperatures up to 170 °C
- | High dimensional stability
- | Available in different colours

TECANYL MT (PPE)

- | Very resistant to gamma radiation, steam autoclave and ethylene oxide (EtO) sterilisation.
- | Compatible with morpholine.
- | Biocompatible
- | Approved for food contact.
- | Low density, therefore lighter weight parts.
- | Good chemical resistance.
- | Dimensional stability in cold and high temperature performance.
- | High impact resistance.

TECAPRO MT (PP)

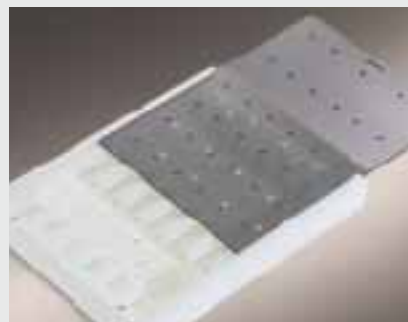
- | Resistant to cleaning agents and disinfectants, hydrolysis and super-heated steam.
- | Heat stabilisation leads to improved resistance to sterilisation, with little warping.
- | Low moisture absorption.
- | Good sliding properties.
- | Easy to machine.

TECAFORM AH MT (POM-C)

- | Good resistance to chemicals.
- | Good electrical insulation.
- | Very good sliding and abrasion properties.
- | Stiff, strong and hard.
- | Easy to machine.
- | Available in different colours.



TECASON P MT / TECANYL MT.
Sizing trials.



TECAPRO MT.
Sterilisation container.



TECAFORM AH MT.
Mouth operated PC mouse from LIFETOOL.



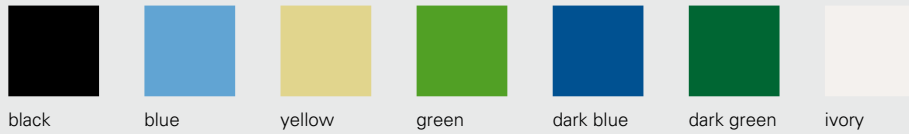
Applications examples for medical plastics

Material	DIN-Abbreviation	Surgical instruments	Containers and trays	Trial implants	Dialysis units	Medicine dosage systems	Dental equipment	Pumps	Housings	Motors	Sterilisation equipment	Grips	Endoscopic instruments	Fixture and drilling units	Analysis and drilling equipment	Anaesthetic equipment
TECAPEEK MT	PEEK	x		x		x	x	x		x	x	x				
TECAPEEK CF 30 MT	PEEK	x									x		x			
TECATRON MT	PPS	x					x		x		x	x		x	x	
TECASON P MT	PPSU	x		x	x	x				x	x	x		x		
TECASON P VF	PPSU		x							x						
TECANYL MT	PPE	x	x	x				x	x	x	x					
TECAFORM AH MT	POM-C			x	x							x				
TECAPRO MT	PP		x					x				x		x		

Many colours for freedom in design

Note: The colour fields are only for comparison. We cannot guarantee the performance of the colours.

TECAPEEK MT (PEEK)



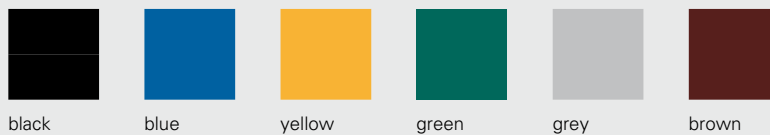
black blue yellow green dark blue dark green ivory

TECASON P MT (PPSU)



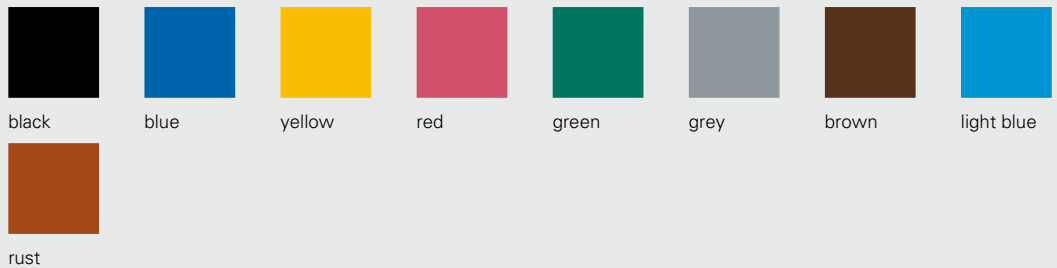
black blue yellow red green grey brown sky blue
rust ivory signal yellow deep orange raspberry red blue lila light green

TECANYL MT (PPE)



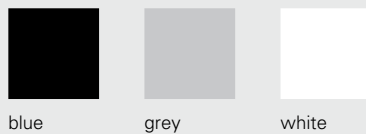
black blue yellow green grey brown

TECAFORM AH MT (POM-C)



black blue yellow red green grey brown light blue
rust

TECAPRO MT (PP)



blue grey white



Use of plastics in food technology and pharmaceuticals



The following materials are suitable for repeated use in contact with foodstuffs and pharmaceuticals, thanks to FDA-conforming raw materials. Due to their high resistance to cleaning agents, even repetitive use is possible.

TECAPEEK (PEEK)

- | Very high resistance to chemicals.
- | Excellent resistance to common methods of sterilisation.
- | Good resistance to radiation.
- | Low susceptibility to stress cracking.
- | High dimensional stability and easy to machine.
- | Excellent tribological properties.
- | Good electrical insulation, even at high voltage.

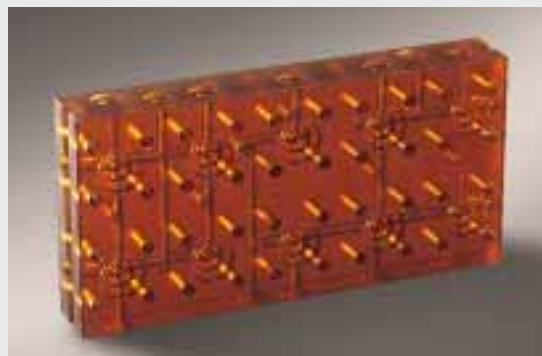
TECAFLON PTFE (PTFE)

- | Maximum resistance to chemicals.
- | Resistant to common methods of sterilisation (except high-energy radiation).
- | Sustained use at a temperature of 260 °C.
- | Excellent sliding properties.
- | Excellent electrical properties.



TECASON P VF.

Inset tray for trial joint implants.



TECASON E.

Dialysis block.



TECANAT PC.

Sealing strips for Siemens CT scanner.



TECANAT PC.

Distributor block.



TECAPET TF.

Slide bar for bottling machine.

TECASON P VF (PPSU)

- | TECASON P MT is specially modified for thermoforming procedures in the production of sterilisation containers.
- | It has the same properties as TECASON P MT (s. page 6).

TECASON E (PES)

- | Translucent.
- | Hydrolysis resistant.
- | Transparent to high frequency electromagnetic waves.
- | High thermal and mechanical stability.
- | Hard and tough.
- | Good electrical and dielectric properties, therefore well suited as an electrical insulator.

TECASON S (PSU)

- | Translucent.
- | Resistant to electromagnetic waves and gamma rays.
- | Hydrolysis resistant.
- | Good thermal and mechanical properties.
- | Good electrical insulation.

TECAFLON (PVDF)

- | Excellent chemical resistance.
- | Very good sterilisation stability (hot steam, cold sterilisation procedures, discoloration possible with gamma sterilization).
- | High temperature stability up to 150 °C.
- | Good slip characteristics.

TECANAT (PC)

- | Translucent.
- | Extremely tough and unbreakable.
- | Excellent electrical insulation.
- | Easy to machine and polish.



TECAMID 66 (PA 66)

- | Good resistance to chemicals.
- | Good electrical insulation. Good stiffness, toughness and resistance to abrasion.
- | Good geometric stability under heat, and easy machining.
- | Good insulation.
- | Good machinability.

TECAPET

- | Good chemical resistance.
- | Low susceptibility to wear in moist or dry surroundings.
- | High dimensional stability through relatively low thermal expansion.
- | Good dielectric characteristics.
- | Low moisture absorption.

TECAFORM AH natural

- | Good resistance to chemicals.
- | Good sliding and wear properties.
- | Good dimensional stability.

TECAFINE PMP (PMP)

- | Low density
- | Low moisture absorption
- | Very good chemical resistance
- | High transparency
- | Partially crystalline

Liquid Silicon Rubber (LSR)

- | High resistance to tear propagation and low permanent set.
- | Hardness adjustable from Shore A 30 to Shore A 71.
- | Components can be injection moulded.

Fields of applications for biocompatible plastics

Material	DIN-Abbreviation	Medicine dosage systems	Analysis equipment	Inspection glass	Water treatment systems	Sanitary ware	Meat processing equipment	Dairy equipment	Kneading machines	Conveyor screws	Housings	Motors	Pumps
TECAPEEK	PEEK	x				x	x					x	
TECAFLON PTFE	PTFE		x										
TECASON P VF	PPSU			x						x			
TECASON E	PES		x	x									
TECASON S	PSU		x	x									
TECAFLON PVDF	PVDF	x	x		x								
TECANAT	PC			x									
TECAMID 66	PA66							x					
TECAPET	PET	x						x	x				
TECAFORM AH	POM-C	x			x			x	x				x
TECAFINE PMP	PMP												
TECAFORM AH SAN	POM-C					x	x						
TECAPRO SAN	PP					x	x						



XRO materials. Good visibility in fluoroscopy and radiography



ENSINGER meets the requirements of minimally invasive and image-controlled surgery with its X-ray opaque XRO plastics. A contrast medium, which is added to the standard product line, gives clear visibility to the components under fluoroscopy and X-ray radiation. It provides the surgeon with an exact picture of his/her instruments or orthopaedic test implants during image-controlled interventions.

Materials available:

TECAPEEK CLASSIX™ XRO (PEEK),
TECASON P MT XRO (PPSU) and
TECANYL MT XRO (PPE).



TECASON P MT XRO. X-ray opaque test implants in different colours.

All these materials have been tested according to the requirements of ISO 10993 for external equipment (communication devices) that is in contact with bodily fluids, bone substance and dentin for less than 24 hours. Semi-finished materials are tested at regular intervals according to ISO 10993-5.

Areas of application

Medical and food technology, precision technology

Characteristics

- | X-ray resistant
- | Raw material and colour additives are biocompatible and FDA-approved
- | Resistant to detergents, disinfectants as well as different solvents
- | Resistant to repetitive autoclaving
- | Highly resistant to gamma radiation
- | Good hydrolysis resistance
- | Outstanding dimensional stability, and very hard and rigid
- | High thermal stability and outstanding mechanical characteristics
- | High impact strength and notched impact strength
- | Low water absorption
- | Very good electrical insulation



SAN materials

Safety for medical technology and the food industry



SAN materials offer additional safety within the field of food processing. The antimicrobial effect is achieved by a continuous release of silver ions onto the surface of the plastic component.

The following materials currently offer antimicrobial protection as standard:

TECAFORM AH MT SAN, TECAPRO MT SAN, TECADUR PBT SAN

Characteristics

- | Higher degree of material purity
 - by reduced bacterial contamination during downtimes
 - decreased formation of biological films on the material surface
 - reduced emergence of bacteria in the case of critical machine geometries (corners, hollows, etc.)
- | Buffer effect in case of incorrect cleaning
- | Even distribution of active substance on the material surface
- | Cleaning or small attrition of the surface provides a continuous renewal of the antimicrobial effect
- | Harmless to humans, as the active substance is not toxic, does not disintegrate into toxic substances or migrate
- | No thermal damage to the active substance within the temperature range of normal applications
- | Raw materials, colour pigments and antimicrobial additives are FDA-approved

Areas of application

Food processing, medical technology, hygiene areas, bottle filling, water technology, sanitary facilities

Notes

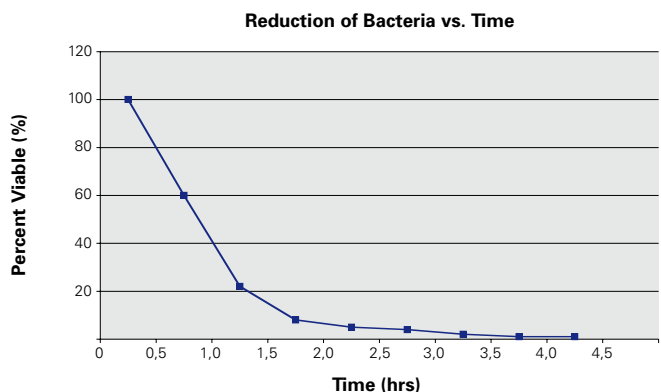
Extreme chemical contamination can lead to impairment of the mode of action of antimicrobial surfaces.

The use of antimicrobial products delays renewed bacterial contamination and thereby provides additional safety.

It is not possible, however, to dispense with normal and usual cleaning provisions.

SAN materials generally work against a wide range of micro-organisms (bacteria, fungi, algae, viruses), but must, nevertheless, still be tested in the specific application in question.

Typical performance of antimicrobial surfaces on bacteria



Consistent quality management



ISO 13485

The demands placed on quality management systems for medical technology are specified by ISO 13485. This international standard describes both the supply of medical devices as well as the associated services. A primary aim is the harmonization of legal requirements for the quality management systems of medical devices.

In doing so, ENSINGER not only satisfies the legal requirements, but the customer can also rely on a certified quality management system.

The following ENSINGER divisions are certified according to ISO 13485:

- | Semi-finished material
- | Injection moulding
- | Industrial profiles
- | Compounding
- | Machine cutting

Traceability

Excellent quality management is also evident with complete traceability. This principle has great importance in medical, pharmaceutical and food technology. Due to consistent documentation of individual process steps, continuous traceability is standard at ENSINGER. Certificates of the respective conformities are only issued according to individual orders at ENSINGER. In this way, a direct reference from certificate to the goods is made.

Packaging

The packaging of medical technology products is an important aspect, in order to protect them against corrosion, contamination and damage.

The product should be protected from high air humidity, dust and dirt, extremes of temperature and direct sunlight during transportation and storage at ENSINGER or at the customer. Depending on the customer's requirements this is provided by using film or blister packaging. These can be adapted flexibly to the product, to some extent even shrunk or used in multiple layers. The product can be cleaned or washed and sterilised, as required. The product is then properly labelled and made ready for shipment in shockproof packaging.

1

At the customer:

The **order** and **invoice number** is on the invoice or delivery note - in the case of semi-finished goods the **batch number** is also on the delivery note. The goods can thus be retraced with these numbers.

Customer Order Invoice
988885 123456 DRA12345

Production no. 12345



Traceability

2

**Finished parts /
Semi-finished material**

A **certificate according to ISO 10204** is issued together with an order. The production or serial number is on the finished part or semi-finished material.



3

**Injection moulding blank /
Semi-finished goods**

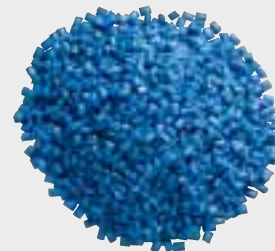
On the basis of **production** and **manufacturing** numbers, it is possible to revert back to the data recorded during the manufacturing process (**production data, manufacturing records, inspection cards**).



4

Compounds

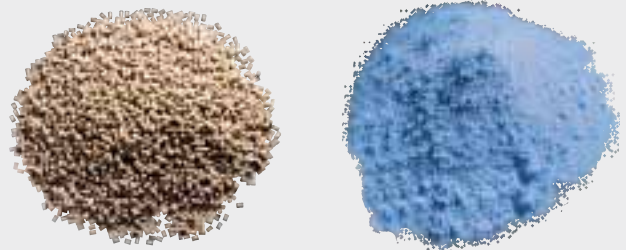
The **lot number** of the compound can be determined from the manufacturing or production number.



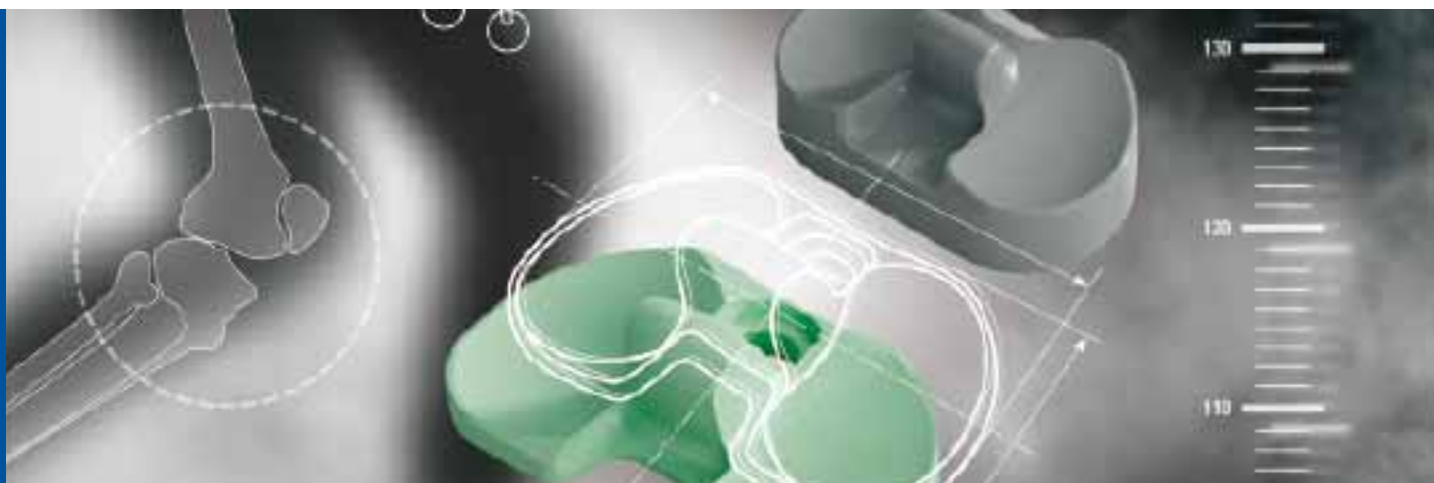
5

Raw materials

The **lot number** of the compound leads to the material prescription and thus to the raw material specification and the safety data sheet of the respective raw ingredients.



Excellent Property Profiles for top Performance in Processing and Use



Resistance against many chemicals

Because of the preparation procedures such as sterilisation and disinfection, medical instruments that are frequently reused must be resistant in many ways.

Material	DIN-Abbreviation	Acids		Bases		Solvents				Water	
		weak	strong	weak	strong	Alcohol	Ester	Ether	Ketone	cold	hot
TECAPEEK CLASSIX™	PEEK	+	o	+	+	+	+	+	+	+	+
TECAPEEK MT	PEEK	+	o	+	+	+	+	+	+	+	+
TECAPEEK CF30 MT	PEEK	+	o	+	+	+	+	+	+	+	+
TECATRON MT	PPS	+	+	+	+	+	+	+	+	+	+
TECASON P MT	PPSU	+	o	+		+			-	+	+
TECAPEI MT	PEI	+	o	-	-	+			-	+	+
TECANYL MT	PPE	+		+						+	+
TECAFORM AH MT	POM-C	+	o	+	-	+	o	o	o	+	+
TECAPRO MT	PP	+	o	+	+	+	o	o	o	+	+
TECAPEEK MT	PEEK	+	o	+	+	+	+	+	+	+	+
TECAFLON PTFE	PTFE	+	+	+	+	+	+	+	+	+	+
TECASON P VF	PPSU	+	o	+		+			-	+	+
TECASON E	PES	+	o	+		o			-	+	+
TECASON S	PSU	+	-	+		o			-	+	+
TECAFLON PVDF	PVDF	+	o	o	-	+		+	o	+	+
TECANAT	PC	o	-	-	-	o	-	-	-	+	o
TECAPET	PET	+	o	o	-	+	o	+	o	+	o
TECAMID 66	PA 66			+	o						
TECAFORM AH	POM-C	+	o	+	-	+	o	o	o	+	+

- + Resistant (Only slight change in weight, if any)
- o Conditionally resistant (Brief contact with the medium possible)
- Not resistant (change in weight > 5 %, severe impairment of the mechanical properties)

Resistance to sterilisation

The deliberate sterilisation of plastic equipment and components serves to kill off all living micro-organisms such as bacteria, viruses, algae and their spores

Hot steam

According to DIN EN 285, all surfaces of the objects for sterilisation must be subjected to pure, saturated water vapour at 134 °C in a vacuum for at least three minutes. Steam sterilisation is regarded as the safest and cheapest method of sterilisation, but the high process temperature makes it less suitable for materials that are sensitive to heat and hydrolysis.

Hot air

In hot-air sterilisation, germs are killed off by means of dry heat under high thermal load (180 °C) over a period of at least 30 minutes. This process is prohibited because of numerous uncertainties. It is no longer up to date, and is therefore usually replaced by other methods.

Plasma

Sterilisation with hydrogen-peroxide plasma is suitable for all plastics, but it is costly and requires elaborate equipment. Highly reactive hydroxy and hydroxyl radicals kill off the micro-organisms at temperatures of only 45 °C over periods of 45 to 80 minutes; the plasma is removed by ventilation. The risk of corrosion is almost non-existent, and there is no toxic residue that would require prolonged degassing.

Formaldehyde and ethylene oxide

Sterilisation by means of a microbiocidal gas such as formaldehyde or ethylene oxide is always carried out at temperatures between 48 and 60 °C. Because of the low temperatures, this process is suitable for temperature-sensitive materials. The efficiency of formaldehyde is comparable with that of ethylene oxide, but its lower toxicity permits shorter degassing times. Both are mainly used for disposable articles.

Sterilisation by radiation

For radiation sterilisation, which is suitable for almost all plastics, either gamma rays or a beam of greatly accelerated electrons are used. These processes are cost and equipment intensive, so they are mainly used for the sterilisation of disposable products on an industrial scale.

Material	DIN-Abbreviation	Hot steam 134 °C	Hot air (approx. 180 °C)	Plasma	Formaldehyde	Ethylene oxide	Gamma radiation
TECAPEEK CLASSIX™	PEEK	++	++	+	+	+	++
TECAPEEK MT, CF30 MT	PEEK	++	++	+	+	+	++
TECATRON MT	PPS	++	++	+	+	+	++
TECASON P MT, P VF	PPSU	+	+	+	+	+	+
TECAPEI MT	PEI	+	+	+	+	+	+
TECANYL MT	PPE	+	-	+	+	+	+
TECAFORM AH MT	POM-C	o	-	+	+	+	-
TECAPRO MT	PP	o	-	+	+	+	-
TECAFLON PTFE	PTFE	++	++	+	+	+	-
TECASON E	PES	+	+	+	+	+	+
TECASON S	PSU	+	o	+	+	+	+
TECAFLON PVDF	PVDF	+	-	+	+	+	+
TECANAT	PC	-	-	+	+	+	+
TECAPET	PET	-	-	+	+	+	+

- + Resistant (Only slight change in weight, if any)
- o Conditionally resistant (Brief contact with the medium possible)
- Not resistant (change in weight > 5 %, severe impairment of the mechanical properties)

FDA conforming materials and biocompatibility

Material	DIN-Abbreviation	FDA conformity ⁽¹⁾	Biocompatibility ⁽¹⁾
TECAPEEK CLASSIX™	PEEK	x	x
TECAPEEK MT	PEEK	x	x
TECAPEEK CF 30 MT	PEEK	(5)	x
TECATRON MT	PPS	(4)	(3)
TECASON P MT	PPSU	x	x
TECAPEI MT	PEI	x	(4)
TECANYL MT	PPE	x	x
TECAFORM AH MT	POM-C	x	x
TECAPRO MT	PP	x	(4)
TECAPEEK	PEEK	x	(3)
TECAFLON PTFE	PTFE	x	(3)
TECASON P VF	PPSU	x	(3)
TECASON E	PES	x	-
TECASON S	PSU	x	(3)
TECAFLON PVDF	PVDF	x	(3)
TECANAT	PC	x	(3)
TECAMID 66	PA 66	x	(3)
TECAPET	PET	x	-
TECAFORM AH	POM-C	x	x
TECAFINE PMP	PMP	x	(3)
TECAPEEK CLASSIX™ XRO	PEEK		x
TECASON P MT XRO	PPSU		(3)
TECANYL MT XRO	PPE		(3)
TECAFORM AH SAN	POM-C	x	
TECAPRO SAN	PP	x	(4)

(1) FDA conformity and biocompatibility apply to natural materials. The pigments used are tested for their suitability according to the FDA regulations. Biocompatibility is not a material specification, and requires prior testing, and if necessary special production.

(2) Applies to MT black, other colours on request
 (3) On request
 (4) Applies to natural, colours on request
 (5) No conformity to FDA possible

FDA Conformity

The American Food and Drug Administration (FDA) assesses the suitability of materials for contact with food. Raw materials, additives and properties of plastics are specified by the FDA in the "Code of Federal Regulations" CFR 21. Materials that meet the relevant requirements are regarded as FDA conforming.

An FDA-conformity formulation is valid without temporary limitation, as long as the raw materials are not changed. For this reason, only the manufacturer of a product may issue this FDA certificate, as only he/she knows the formulation and can guarantee that FDA-conforming raw materials are used. In order to ensure complete traceability of medical devices, this certificate should always be issued in relation to specific orders.

According to FDA regulations, **carbon fibres** are not specified in the list, i.e. FDA conformity cannot be issued. The German Federal Institute for Risk Evaluation (BfR) classifies carbon fibres as physiologically harmless. Carbon fibres do not emit gases and are very resistant towards chemicals used in food and medical technology products.

Biocompatibility

Biocompatibility is the measure of the compatibility of a material with the tissue or physiological system of the patient. Assessment involves a number of investigations as defined in USP (U.S. Pharmacopeia) Class VI or ISO 10993.

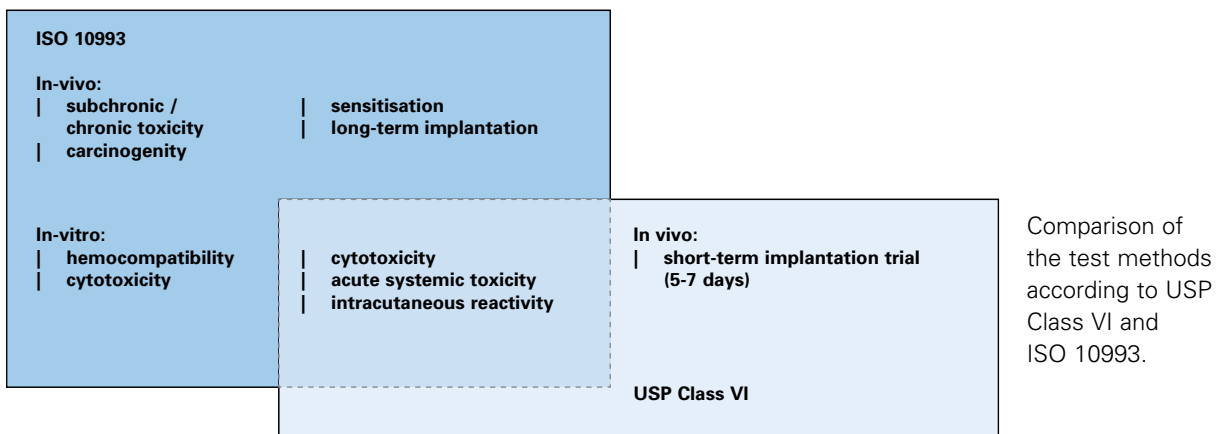
Biocompatibility depends not only on the type of material, but also on:

- | Where it is used (skin, mucous membranes, blood, tissue)
- | The intended function (superficial contact with the body, contact with the interior of the body, implantation)
- | The length of time that the material remains in the body (< 24 hours, < 30 days, indefinitely)

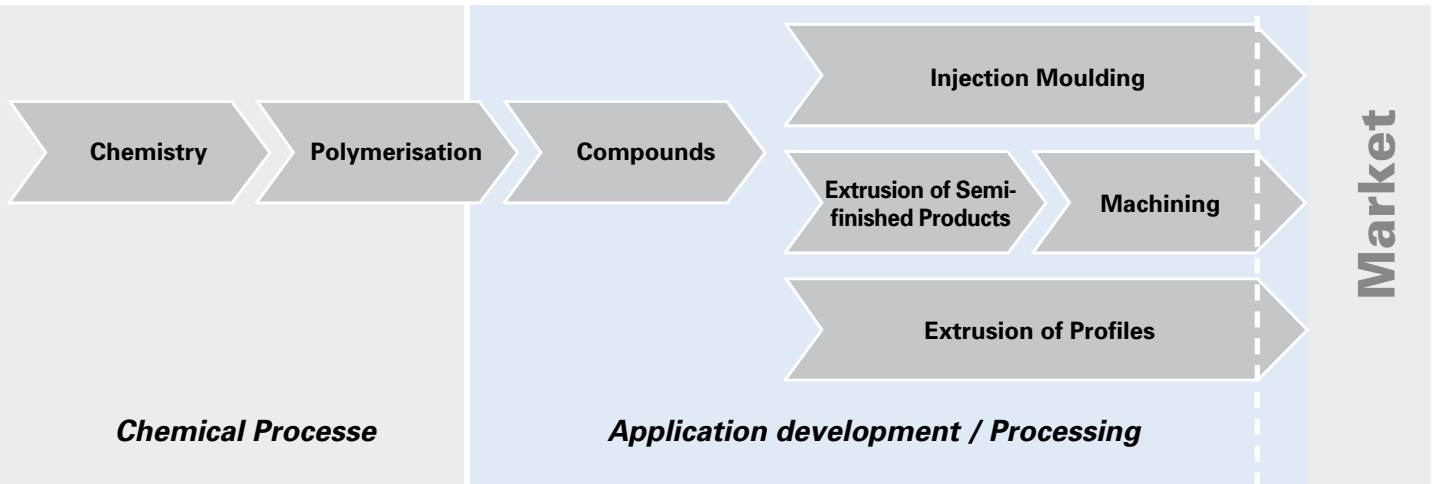
Testing for cytotoxicity is considered standard for medical devices and is carried out at ENSINGER on semi-finished materials at regular test intervals. The contact of an extracted solution with cell cultures is used to detect toxic substances, which could be released from the material during use. In this way, a substantiated statement about the physiological safety of the material is possible.

Traceability

An FDA certificate should always be issued in direct relation to an order and the respective material supplied, in order to ensure complete traceability of medical devices. This minimizes the danger that FDA non-conforming, specially produced materials are accidentally provided with FDA certificates and as such are released to the market, which can be the case with uncontrolled downloads from the Internet.



Safety in many different areas of medical technology

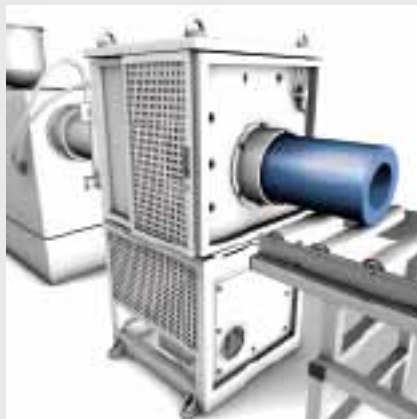


ENSINGER MT plastics are made of FDA-approved raw materials. They are also tested for their biocompatibility on semi-finished products at regular intervals. These particular characteristics and the specific sterilisation stability predetermine their use in the area of medical and pharmaceutical technology.

Our project partners profit from the vast experience that ENSINGER possesses in different areas of medical technology. ENSINGER finds the optimal solution for each defined application by detailed consideration of every special requirement. This application-oriented project management approach includes



Compounds



Extrusion



Machining

Compounds

In compounds, plastic raw materials are combined with fillers or additives, extruded to give thin strands and then cut into granulate. With this process, the characteristics of the plastics can be adapted for a special application, e.g. by improving the sliding friction characteristics or increasing the electrical conductivity.

Extrusion

The pressure and temperature-controlled extrusion process gives semi-finished goods and profiles an even and low-stress structure. ENSINGER processes a broad spectrum of engineering and high temperature polymers. The semi-finished materials portfolio consists of rods, tubes and plates in many different dimensions and colours.

Machining

By milling, turning, drilling and other mechanical procedures in the machining process at ENSINGER, precise and dimensionally stable finished parts are made out of semi-finished materials.

Injection Moulding

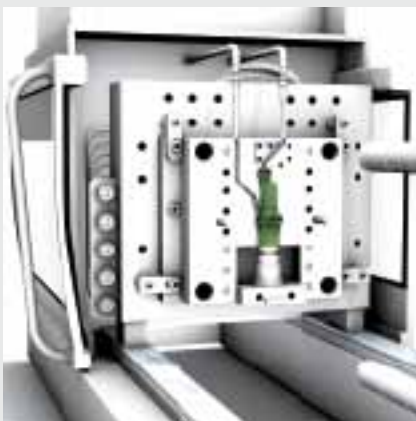
The use of the latest technology, the versatility of the materials and many years of experience in processing are crucial advantages in injection moulding manufacture at ENSINGER.

Custom Cast

Pressure-free finished casting has proved to be particularly successful in the production of large-volume cast parts, which are almost finished. The custom cast process is particularly suitable for low-stress, thick-walled parts with large dimensions.

Industrial Profiles

Profiles are subjected to frequent high mechanical, thermal or chemical stresses. ENSINGER products are used in almost all industrial areas, for example, as insulation profiles in window construction or as precision profiles in aeronautics.



Injection moulding



Custom cast



Extrusion of profiles

ENSINGER Engineering plastics. Material standard values.

Mechanical properties

Trade name	DIN-Abbrev.	Additives, colours	Long term service temperatur °C	ρ g/cm ³	σ_S MPa	σ_R MPa	ϵ_R %	E_z MPa	E_B MPa	H_K MPa	a_n kJ/m ²	$\sigma_{B/1000}$ MPa	$\sigma_{1/1000}$ MPa	μ	V µ/km	Trade name
TECAPEEK CLASSIX™	PEEK	white	260	1,38	95		> 25		4200		7,6 (d)					TECAPEEK CLASSIX™
TECAPEEK MT	PEEK	coloured, also black ⁽¹⁾	260	1,30	95			3000	4100	M99 (r)	n. br. (c)			0,30-0,38		TECAPEEK MT
TECAPEEK CF 30 MT	PEEK CF30	black ⁽¹⁾	260	1,40		160	3	14500			50 (c)					TECAPEEK CF 30 MT
TECATRON MT sw	PPS	black ⁽¹⁾	230	1,35	75		4	3700	3600	190	50 (c)					TECATRON MT sw
TECASON P MT	PPSU	coloured, also black ⁽¹⁾	170	1,29	70		> 50	2350	2600	31	n. br. (c)					TECASON P MT
TECAPEI MT	PEI	coloured	170	1,27	105			3200	3300	140	4 (c)					TECAPEI MT
TECANYL MT	PPE	coloured, also black ⁽¹⁾	95 ^(a)	1,08	67	55	16,3	3240	2540		293 (ai)					TECANYL MT
TECAFORM AH MT	POM-C	coloured, also black ⁽¹⁾	100	1,41	55		30	2100		145	n. br. (c)	40	13	0,32	8,9	TECAFORM AH MT
TECAPRO MT	PP	white, grey, black ⁽¹⁾	100	0,92	35			1300	1470	100 (r)	41,9 (ai)					TECAPRO MT
TECAPEEK	PEEK	natural	260	1,30	95		25	3000	4100	M99 (r)	n. br. (c)			0,30-0,38		TECAPEEK
TECAFLON PTFE	PTFE	natural	260	2,18	25		> 50	700		30	n. br. (c)	5	1,58	0,08/0,10	21	TECAFLON PTFE
TECASON P VF	PPSU	coloured	170	1,29	70		> 50	2350	2600							TECASON P VF
TECASON E	PES	translucent	180	1,37	90		40	2700		148	n. br. (c)		20			TECASON E
TECASON S	PSU	translucent	160	1,24	80		> 50	2600		147	n. br. (c)	42	22	0,4		TECASON S
TECAFLON PVDF	PVDF	natural	150	1,78	50		> 30	2000	2000	80	n. br. (c)	34	3	0,3		TECAFLON PVDF
TECANAT	PC	translucent	120	1,20	60		130	2300		100	n. br. (c)	48	18	0,52-0,58	22	TECANAT
TECAMID 66	PA 66	natural, also black ⁽¹⁾	100	1,14	80/60*		40/150*	3100/2000*	2830	170/100*	n. br. (c)	55	8	0,35-0,42	0,9	TECAMID 66
TECAPET	PET	natural, also black ⁽¹⁾	110	1,37	88			3200		170	n. br. (c)		13	0,25	0,35	TECADUR PET
TECAFORM AH	POM-C	natural, also black ⁽¹⁾	100	1,41	62		30	2700		145	n. br. (c)	40	13	0,32	8,9	TECAFORM AH
TECAFINE PMP	PMP	translucent	120	0,83				1500		85	n. br. (c)					TECAFINE PMP
TECAPEEK CLASSIX™ XRO	PEEK	white	260	1,65		80	2	5000	4000		14 (c)					TECAPEEK CLASSIX™ XRO
TECASON P MT XRO	PPSU	coloured, also black ⁽¹⁾	170	1,30	70		> 50	2000	2100	122,5 (r)						TECASON P MT XRO
TECANYL MT XRO	PPE	coloured, also black ⁽¹⁾	95 ^(a)	1,08	67	55	16,3	3240	2540		293 (ai)					TECANYL MT XRO
TECAFORM AH SAN	POM-C	white	100	1,41	62		30	2700		145	n. br.	40	13	0,32	8,9	TECAFORM AH SAN
TECAPRO MT SAN	PP	white	100	0,92	35			1300	1470	100 (r)	41,9 (ai)					TECAPRO MT SAN

Conditions of Delivery can be found in our Semi-finished products catalogue or at www.ensinger-online.com. This information corresponds with current knowledge, and indicates our products and possible applications. We cannot give you a legally binding guarantee of physical properties or suitability for a specific application. Existing commercial patents are to be taken into account. A definite quality guarantee is given in our general conditions of sale. Tests are carried out in a standard atmosphere of 23 °C 50 RH according to DIN 50 014. We reserve the right to make technical alterations. Our products are not destined for use in medical and dental implants.

MT products

We expressly wish to point out that our technical plastics for medical use are only suitable for and intended to come temporarily into contact with human blood or tissue in the sense of the European Union guideline 93/42/EWG for medical devices. In particular, use is not permitted as an implantable product in the sense of the guideline.

TECAPEEK CLASSIX™

Products made of TECAPEEK CLASSIX™ can be used for your applications which have only intentional short-term contact with human blood or tissue in the sense of the above-mentioned guideline.

PEEK OPTIMA

In case of longer term contact and/or implantable products, please refer to PEEK OPTIMA from INVIBIO® Ltd.



Trade name	Thermal properties										Electrical properties						Miscellaneous data				
	T_m °C <small>Melting point (DIN 53 765)</small>	T_g °C <small>Glass transition temperature (DIN 53 765)</small>	HDT/A °C <small>Heat distortion temperature DIN EN ISO 75 method A</small>	HDT/B °C <small>Heat distortion temperature DIN EN ISO 75 method B</small>	°C <small>Service temperature short term</small>	λ W/(K·m) <small>Thermal conductivity (23°C)</small>	c J/(g·K) <small>Specific heat (23°C)</small>	α 10^{-5} 1/K <small>Coefficient of linear thermal expansion (23°C, ASTM D 695, DIN ISO 7591, ASTM E 831)</small>	ϵ_r - <small>Dielectric constant (10³ Hz, ASTM D 150, DIN 53 483, IEC 60093)</small>	$\tan \delta$ - <small>Dielectric loss factor (10³ Hz, ASTM D 150, DIN 53 483, IEC 60093)</small>	ρ_o $\Omega \cdot \text{cm}$ <small>Surface volume resistance (ASTM D 257, IEC 93, DIN IEC 60093)</small>	R_o Ω <small>Surface resistance (ASTM D 257, IEC 93, DIN IEC 60093)</small>	E_d kV/mm <small>Dielectric strength (ASTM D 149, DIN EN 60093)</small>	Grade	W(H ₂ O) % <small>Resistance to tracking DIN EN 60 112, VDE 0303 Teil 1)</small>	W _s % <small>Water absorption to equilibrium 23 °C/50% rel. humidity (DIN EN ISO 62)</small>	- <small>Resistance to hot water washing soda</small>	- <small>Resistance to hot water washing soda</small>	- <small>Flammability acc to UL-Standard 94</small>	- <small>Resistance to weathering[®]</small>	Tradename
TECAPEEK CLASSIX™	343	143			300																TECAPEEK CLASSIX™
TECAPEEK MT	343	143	140	182	300	0,25	0,32	5,0	3,2-3,3	0,001-0,004	10 ¹⁶	10 ¹⁵	20		0,1	0,5	+	V0	-	TECAPEEK MT	
TECAPEEK CF 30 MT	343	143	315		300										0,1	0,1	+	V0	+	TECAPEEK CF 30 MT	
TECATRON MT sw	280	90	110		260	0,25		5			10 ¹³	10 ¹⁵			0,01		+	V0	-	TECATRON MT sw	
TECASON P MT		220	207	214	190	0,35		5,6	3,45		10 ¹⁵	10 ¹³	15		0,37	1,1	+	V0	-	TECASON P MT	
TECAPEI MT		217	180	200	200	0,22		5	3,15	0,001	10 ¹⁵	10 ¹⁵	33		0,7	1,25	+	V0	-	TECAPEI MT	
TECANYL MT			147		140			9							0,06	0,23	+			TECANYL MT	
TECAFORM AH MT	165	-60	110	160	140	0,31	1,5	10	3,5	0,003	10 ¹⁴	10 ¹⁴	> 50	KA 3c	< 0,3	0,5	(+)	HB	-	TECAFORM AH MT	
TECAPRO MT	163																				TECAPRO MT
TECAPEEK	343	143	140	182	300	0,25	0,32	5,0	3,2-3,3	0,001-0,004	10 ¹⁶	10 ¹⁵	20		0,1	0,5	+	V0	-	TECAPEEK	
TECAFLON PTFE	327	-20	55	121	260	0,25	1	12	2,1	0,0002	10 ¹⁶	10 ¹⁶	48	KA 3c KB>600	< 0,05		+	V0	+	TECAFLON PTFE	
TECASON P VF		220	207	214	190	0,35		5,6	3,45		10 ¹⁵	10 ¹³	15		0,37		+	V0	-	TECASON P VF	
TECASON E		225	204	214	220	0,18	1,12	5,5	3,5	0,005	10 ¹⁶	10 ¹⁴	40		0,7	2,1	+	V0	-	TECASON E	
TECASON S	188	180	169	181	180	0,25	1	5,5	3,1	0,005	10 ¹⁶	10 ¹⁴	42	KA 1 KB 175	0,2	0,8	+	V0	-	TECASON S	
TECAFLON PVDF	172	-41	95	140	150	0,11	1,2	13	8	0,06	10 ¹⁴	10 ¹³	10-60	KA 1	<0,05	<0,05	+	V0	+	TECAFLON PVDF	
TECANAT		148	135	140	140	0,19	1,2	7	3	0,006	10 ¹³	10 ¹⁵	27	KA 1	0,15	0,36	-	HB	-	TECANAT	
TECAMID 66	260	72/5*	100	>200	170	0,23	1,7	8	3,6-5	0,026-0,200	10 ¹²	10 ¹⁰	28*/30	CTI 600	2,8	8,5	(+)	HB	-	TECAMID 66	
TECAPET	255	70	95	170	170	0,24	1,1	7	3,2	0,0021	10 ¹³	10 ¹⁵	60	KC 350	0,25	0,5	-	HB		TECAPET	
TECAFORM AH	165	-60	110	160	140	0,31	1,5	10	3,5	0,003	10 ¹⁴	10 ¹⁴	>50	KA3c	<0,3	0,5	(+)	HB	-	TECAFORM AH	
TECAFINE PMP	245	20	51	85		0,17	2,18	12	2,12		10 ¹⁴	10 ¹³	65	KA 3c KC=600 KB>600	<0,05	0,01	+	HB	-	TECAFINE PMP	
TECAPEEK CLASSIX™ XRO					260								>10 ¹²				<0,5			TECAPEEK CLASSIX™ XRO	
TECASON P MT XRO		220	207	214	190			5,6	3,45				15		0,37	1,1	+	V0	-	TECASON P MT XRO	
TECANYL MT XRO			147		110			9							0,06	0,23	+			TECANYL MT XRO	
TECAFORM AH SAN		-60	110	160	140	0,31	1,5	10	3,5	0,003	10 ¹⁴	10 ¹⁴	>50	KA3c	<0,3	0,5	(+)	HB	-	TECAFORM AH SAN	
TECAPRO MT SAN	163																				TECAPRO MT SAN

Note: For polyamides the values strongly depend on the humidity contents.

* humid, after storage in standard atmosphere 23 °C 50 RH (DIN 50 014) until saturation.

n. br. = not broken
+ = Resistant
(+) = Limited resistance
- = Not resistant
(depending on concentration, time and temperature)

- (1) When plastics are listed under „additives and colour“ as available „also in black“, the electrical properties are not valid for the black variant.
- (2) Testing on semi-finished products.
- (3) Expected values.
- (4) Impact resistance is measured with different methods. The values in the following tables are marked with the following letters:
(c) Charpy: DIN EN ISO 179; a_n kJ/m²
(ai) Izod: ASTM D 256; a_n J/m
(di) Izod: DIN EN ISO 180; a_n kJ/m²
(k) Notch impact strength: DIN EN ISO 179; a_n kJ/m²

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