BASF
We create chemistry

Engineering Plastics for Medical Solutions

Ultraform® PRO (POM) and Ultradur® PRO (PBT)

Innovation means
that we care.

BASF's PRO Grades Ultraform® and Ultradur®

Reliable plastic products for patient's safety

BASF offers all-round solutions to meet highest market demands and has therefore shaped the history of plastics and continues to do so. Therefore the company is far more than the well-known global plastics supplier.

By understanding the increasing customer demands in medical applications with high-performance profiles and long-term formulation consistency, BASF prompted to extend its portfolio of engineering plastics for medical technology and industry needs.

Ultraform® PRO (POM) and Ultradur® PRO (PBT) were specifically developed to meet the requirements and needs of the challenging and at the same time risk-averse medical market.

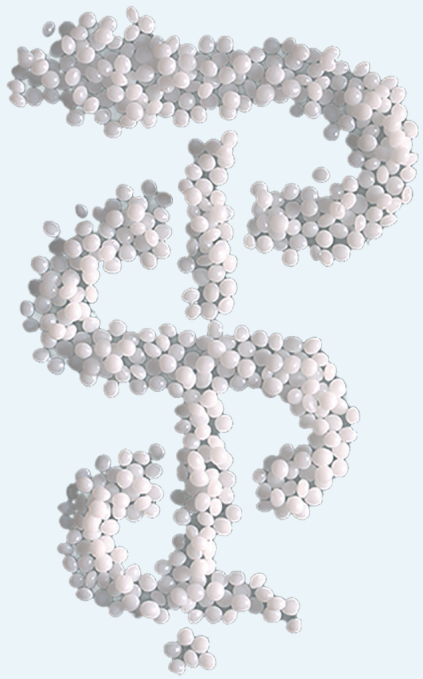
The suffix **PRO** (**P**rofile covered **R**aw materials **O**nly) points to the fact that only controlled raw materials are being used within the enhanced production process, in combination with testing procedures. Furthermore, the service package around the PRO grades assures reliable change control and accordance to regulatory pharmaceutical and medical industry specific expectations. The PRO package fulfills all essential steps for untroubled production of safe medical devices.

Bring us your ideas, we'll help you turn them into real solutions.

At BASF – Innovation means that we care.

Our competencies for the medical industry

- Deep industry knowledge and understanding
- Dedicated global medical team
- Customized solutions
- Strong R&D power
- Global network and presence



PRO service package

Safety for patients, reliability for processors

Commitment

- High quality and **product purity**
- **Consistent formulation** according to Drug Master File (DMF)
- Long-term **supply assurance**
- Advanced **change notification** process **(36 months)**
- **Change management** procedures

Handling

- Production conditions according to **GMP** principles*
- Dedicated **production line concept** and enhanced quality control procedures for raw material and final product
- Back up production line concept **(security of supply)**
- **Sample retention** and documentation
- Effective **risk management** procedures

Regulation

- Support of global **regulatory approvals** for pharmaceutical and medical applications
- Material compliance to **FDA** and **EU** requirements
- Certified **Biocompatibility (USP Class VI / ISO 10993)**
- **Drug Master File** (DMF) listing
- Latex free, ROHS, Phthalate free (REACH compliant)

Support

- Increased **technical support** (color trend, design assistance, analytical testing, calculation (FEM), simulation / filling studies (mold flow), individual part testing, processing guidance, troubleshooting etc.)
- Extensive **research and development** capabilities
- Testing the **compatibility** of the plastic to specific chemicals
- **Plant audits**
- Access to over **50 years** of application innovation in different industry areas

*Commission regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

Ultraform® PRO & Ultradur® PRO at a glance

High performance plastics with highest formulation consistency

Ultraform® PRO (POM, copolymeric polyoxymethylene) is a semi-crystalline engineering plastic.

General Property Profile

- High crystallinity
- Ideal combination of strength, stiffness and toughness
- Outstanding tribological properties, e.g. low friction and wear, very good sliding properties
- Excellent thermal and oxidative stability, high resistance to heat deflection (continuous temperatures of up to 100 °C)
- Very good resilience (spring properties)
- High dimensional precision and stability
- Excellent chemical and hydrolysis resistance
- Good processability

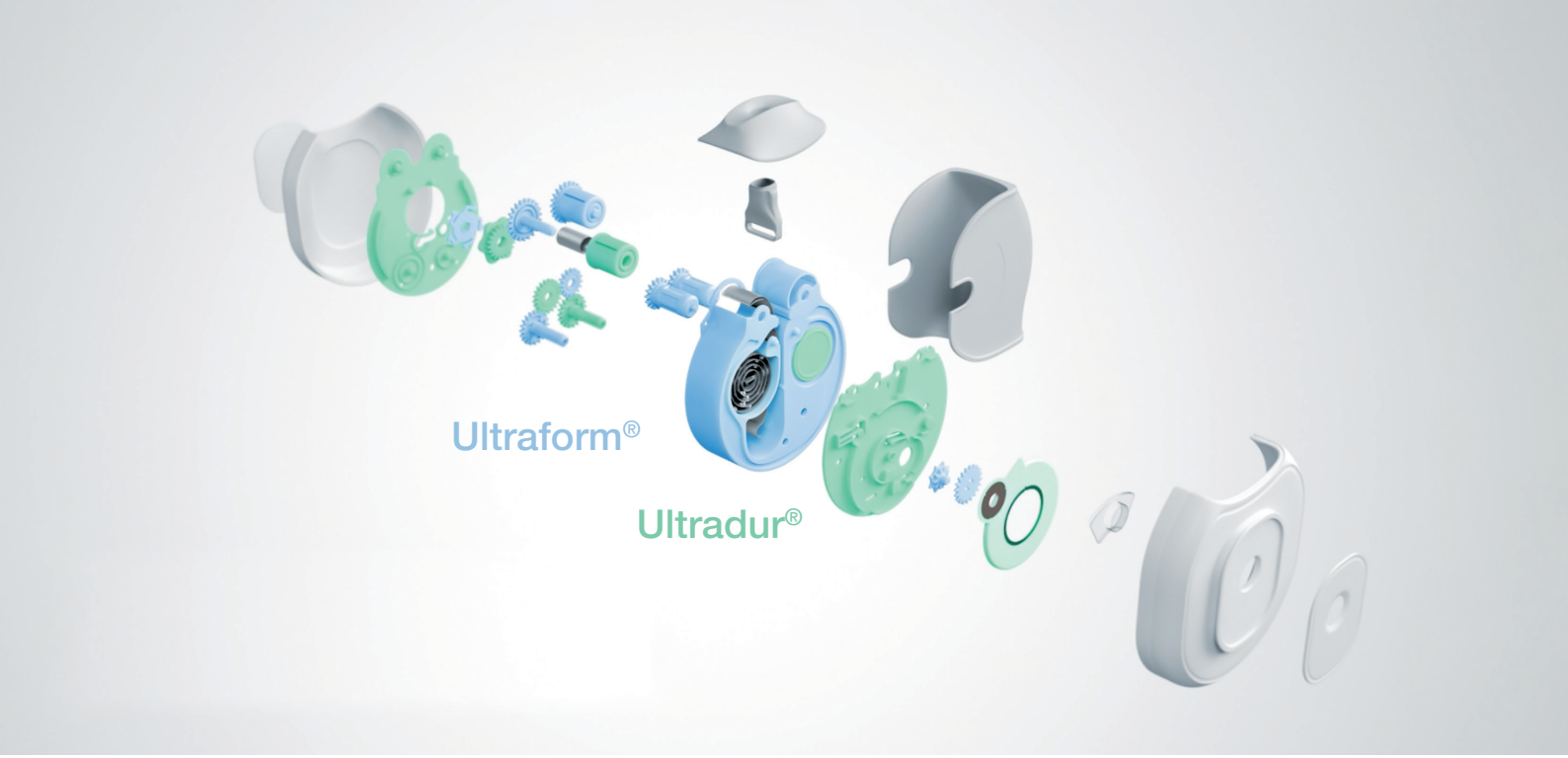
Ultraform® PRO	Description
N2320 003 PRO AT	Standard flow, unreinforced / unfilled
S1320 003 PRO AT	Easy flow, unreinforced / unfilled, increased stiffness
S2320 003 PRO AT	Easy flow, unreinforced / unfilled
S2320 003 PRO TR AT	Easy flow, tribological modified
W2320 003 PRO AT	Very easy flow, unreinforced / unfilled
W2320 003 PRO TR AT	Very easy flow, tribological modified

Ultradur® PRO (PBT, polybutylene terephthalate) is a semi-crystalline engineering plastic, which is part of the polyester family of resins.

General Property Profile

- High dimensional stability due to improved shrinkage behavior
- Ideal sliding and wear resistance
- Broad chemical resistance to polar and non-polar solvents
- High reproducibility and accuracy in molding parts
- Low water / moisture absorption
- Excellent heat aging behavior
- Good moldability with fast cycles

Ultradur® PRO	Description
B4521 PRO	Standard flow, unreinforced / unfilled



Tribological modified Ultraform® PRO TR grades are including a special lubricant which offers improved sliding properties in terms of exceptional low friction and low wear properties in complex mechanical devices.

Tribological benefits:

- No squeaking or noise during use
- Suitable for dry run applications
  - No external lubrication required → elimination of post siliconization process steps in production
- No running-in effects
  - Smooth-running operation from the beginning
- Low breakaway forces

Resistance to sterilization of Ultraform® PRO and Ultradur® PRO

	Superheated steam			Irradiation		Gas	Plasma
	121 °C	134 °C	143 °C	Gamma	Electron Beam	Ethylene Oxide	
Ultraform® PRO	o*	o*	-*	o	o	+	+
Ultradur® PRO	o*	-*	-*	+	+	+	o

+ = full resistance o = limited resistance - = No resistance
*Superheated steam resistance is dependent on conditions → duration and number of cycles

Application area

PRO grades are applicable in a very broad spectrum

With their high mechanical and tribological performance, Ultraform® PRO and Ultradur® PRO are suitable for all functional and mechanical components used in medical applications.

Sliding mechanisms

Medical fluid control applications

Surgical instruments

Diagnostic devices

Metal gear replacement

Filter systems

Inhalers

Auto-injectors

Chassis and Housings

Tribological systems

Pharmaceutical closures

Clips and clamps

Insulin pens

Aerosol valves

Snap Fittings

Lancing devices

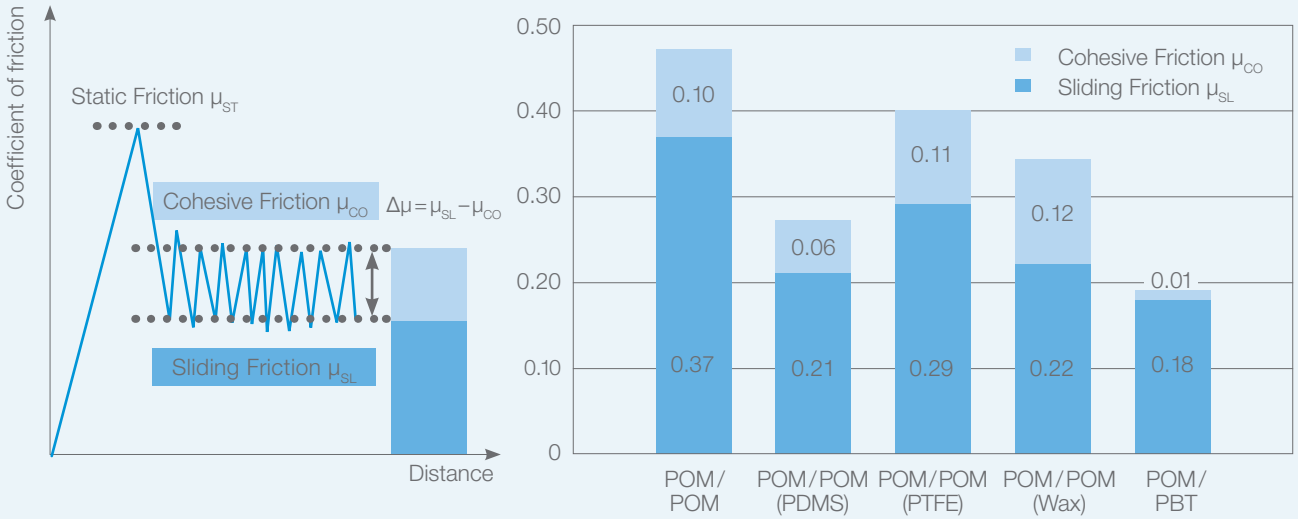
Innovative ideas and synergy effects

Ultraform® PRO and Ultradur® PRO go hand in hand for optimized application performance

Tribological pairing

The pairing of components made of standard Ultraform® PRO and Ultradur® PRO offers additional tribological synergy effects: smooth-running operation and low noise thanks to a smart product combination.

Stick-Slip Test



Test conditions: v = 2 mm/s; p = 0.015 MPa; (23 °C, technically dry, contact area: 200 mm²)

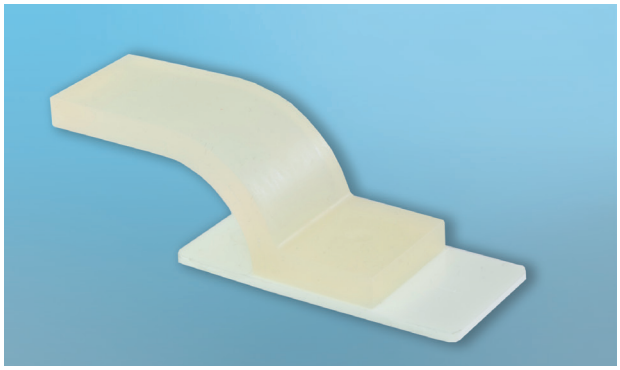
The lower Δμ, the lower is the probability of stick-slip and squeaking!

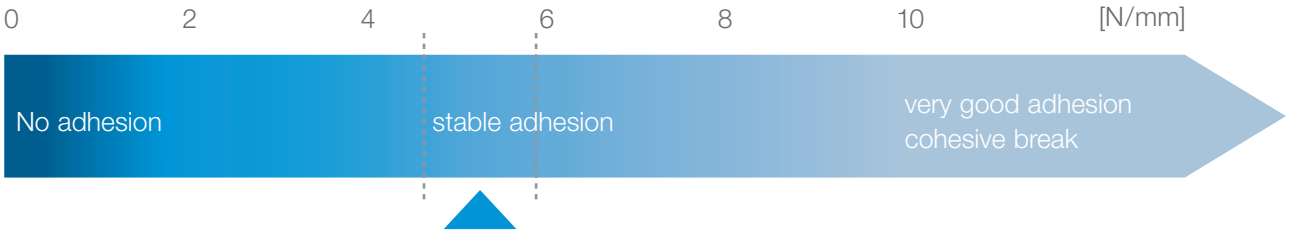
Marking

Markings on medical or drug delivery devices are necessary for identification reasons or to display the dosing scale. These components can be applied by laser marking, pad printing or hot stamping. Especially laser marking and pad printing enable durable, high-contrast markings for both functional and decorative purposes. Due to software solutions laser marking is very flexible to implement design changes and allows marking even on locations that are hard to access without solvents.

Hard-soft combination

The possibility to pair two components made of hard plastics (engineering plastics) and soft plastics (LSR, TPU, TPE etc.) by injection molding is rapidly gaining importance for medical applications, e.g. seals, damping elements and slip-resistant or shock-absorbing surfaces. The all-in-one-production minimizes costs, and enables high design freedom, even for multifunctional parts.





Peeling force range of medical Silopren™ LSR 47x9 series & Ultradur® PRO, Silopren™ is a trademark of Momentive Performance Materials Inc.

Sustainability

BASF is driving circular economy by making the most of the limited resources of our planet: We keep them in use for as long as possible, minimize waste and create value with renewable resources. In ChemCycling®, BASF uses recycled feedstock derived from plastic waste for our broad Ccycled® product portfolio, replacing virgin fossil resources at the beginning of BASF´s value chain. BASF's biomass balance (BMB) approach contributes to the use of renewable raw materials in its integrated production system and can be applied to the majority of the products in its portfolio.

Biomass balanced solutions save fossil resources and reduces the carbon footprint of BMB products compared to the conventional equivalent.

Annotation

What you should further know about our mode of operation

BASF produces a wide variety of high-quality materials that satisfy the manifold requirements of our customers, including products that may meet the technical specifications for use in medical devices and pharmaceutical applications. BASF has proven expertise in supporting and working with our customers in the innovative use and application of our materials.

BASF provides a product information to the customer after an evaluation that the planned application is supported by BASF. This enables the customer to determine whether the product is suitable for his medical device application.

The suitability of a BASF product in a given end-use environment is dependent on various conditions including, chemical compatibility, method of manufacture, temperature, part design, sterilization method, residual stresses and external loads. It is the manufacturer's responsiblity of the final product to determine the suitability (without limitation concerning biocompatibility) of all raw materials and components, including any BASF products.

It also is the sole responsibility of the final product's manufacturer to conduct all necessary tests and inspections. Furthermore, the final product has to be evaluated under recent end-use requirements. It is the duty of the manufacturer to adequately advise and warn purchasers, users and/or learned intermediaries (such as physicians) of pertinent risks and to fulfill any post-market surveillance obligations.

BASF does not supply its plastics for the production of medical devices that are intended as an implant into the human body (meant to stay in the human body for more than 30 days). BASF expressively advises against plastics supplied for other purposes being used for these medical applications.

Engineering Plastics for Medical Solutions

Ultraform® PRO (POM) and Ultradur® PRO (PBT)

Typical values for uncolored products at 23 °C	Unit	Test method	Ultraform® N2320 003 PRO AT	Ultraform® S1320 003 PRO AT
Properties				
Polymer abbreviation	–	–	POM	POM
Density	kg/m³	ISO 1183	1410	1410
Melt volume rate MVR*	cm³/10 min	ISO 1133	7.5	11
Melt flow rate MFR (190 °C/2.16 kg)	g/10 min		8.8	13
Reinforcing material	–	–	without	without
Water absorption, equilibrium in water at 23 °C	%	similar to ISO 62	0.9	0.9
Moisture absorption, equilibrium 23 °C/50 % r. h.	%	similar to ISO 62	0.2	0.2
Processing				
Processing: Injection molding (M), Extrusion (E), Blow molding (B)	–	–	M	M
Pre-drying temperature	°C	–	100**	100**
Pre-drying time	h	–	3**	3**
Max. residual moisture content	%	–	0.2**	0.2**
Melt temperature, injection molding, range	°C	–	190 - 230	190 - 230
Mold temperature, injection molding, range	°C	–	60 - 120	60 - 120
Molding shrinkage (parallel)	%	ISO 2577, 294-4	2.1	2.1
Molding shrinkage (normal)	%	ISO 2577, 294-4	2.1	2.1
Mechanical Properties				
Tensile modulus	MPa	ISO 527-1/-2	2700	3000
Yield stress, 50 mm/min	MPa	ISO 527-1/-2	64	67
Yield strain, 50 mm/min	%	ISO 527-1/-2	10.7	10.5
Nominal strain at break, 50 mm/min	%	ISO 527-1/-2	32	25
Tensile creep modulus (1h)	MPa	ISO 899-1	1800	–
Tensile creep modulus (1,000 h)	MPa	ISO 899-1	1450	1450
Charpy unnotched impact strength	kJ/m²	ISO 179/1eU	270	230
Charpy unnotched impact strength (-30 °C)	kJ/m²	ISO 179/1eU	250	210
Charpy notched impact strength (23 °C)	kJ/m²	ISO 179/1eA	6.5	6
Charpy notched impact strength (-30 °C)	kJ/m²	ISO 179/1eA	5.5	5.5
Ball indentation hardness at 358 N and 30 s	MPa	ISO 2039-1	135	150
Thermal Properties				
Melting temperature, DSC (20 °C/min)	°C	ISO 11357-1/-3	166	170
HDT A (1.80 MPa)	°C	ISO 75-1/-2	95	100
HDT B (0.45 MPa)	°C	ISO 75-1/-2	156	159
Vicat softening temperature (50 °C/h, 50 N)	°C	ISO 306	150	150
Max. service temperature (short cycle operation)	°C	–	100	100
Coefficient of linear thermal expansion, longitudinal (23 - 55 °C)	10^{-6}/K	ISO 11359-1/-2	110	110
Compliance – pharmaceutical/medical				
USP Class VI			Yes	Yes
Cytotoxicity (ISO 10993-5)			Yes	Yes
Drug Master File (DMF)			34139	33419
Compliance – food contact				
European Food Contact Regulations: Commission Regulation (EU) No 10/2011			Yes	Yes
US FDA Regulations: 21 CFR and/or Food Contact Notifications			§ 177.2470	§ 177.2470

* Melt volume-flow rate MVR according to ISO 1133:
- Ultraform® PRO: 190 °C and 2.16 kg
- Ultradur® PRO: 250 °C and 2.16 kg

** Granules or pellets of Ultraform® PRO in original packaging can be processed without any special pre-treatment. Granules or pellets which have become moist due to prolonged or incorrect storage (e. g. by formation of condensed water) must be dried in dehumidifying or re-circulating air dryers according to the above recommended conditions.

	Ultraform® S2320 003 PRO AT	Ultraform® S2320 003 PRO TR AT	Ultraform® W2320 003 PRO AT	Ultraform® W2320 003 PRO TR AT	Ultradur® B4521 PRO
	POM	POM	POM	POM	PBT
	1410	1400	1410	1380	1300
	11	11	25	25	25
	13	13	30	–	–
	without	without	without	without	without
	0.9	0.8	0.8	0.8	0.5
	0.2	0.2	0.2	0.2	0.25
	M	M	M	M	M, (E)
	100**	100**	100**	100	80 - 120
	3**	3**	3**	3	4
	0.2**	0.2**	0.2**	0.2	0.04
	190 - 230	190 - 230	190 - 230	190 - 230	250 - 270
	60 - 120	60 - 120	60 - 120	60 - 120	40 - 70
	2.1	2.2	2	2.0	2.1
	2.1	2	2.1	1.9	2.5
	2700	2600	2850	2500	2650
	64	62	65	50	60
	10	9	8	5.5	10.8
	29	35	24	37	30
	1900	–	2100	–	–
	1300	–	1350	–	–
	250	180	190	110	228
	230	145	190	95	140
	6	5.5	4.5	5	3.5
	5.5	6	4	4.4	3
	145	135	145	125	135
	167	167	166	167	223
	100	100	100	92	55
	167	–	156	–	155
	150	–	150	–	188
	100	100	100	100	200
	110	120	110	125	–
	Yes	Yes	Yes	–	Yes
	Yes	Yes	Yes	–	Yes
	33741	34209	33801	–	34143
	Yes	Yes	Yes	Yes	Yes
	§ 177.2470	§ 177.2470	§ 177.2470	§ 177.2470	§ 177.1660

Selected Product Literature for Ultradur® and Ultraform®:

- Ultradur® – Product Brochure
- Ultradur® – Product Range
- Ultraform® – Product Brochure
- Ultraform® – Product Range
- Ultramid®, Ultradur® and Ultraform® – Resistance to Chemicals

Note

The data contained in this publication are based on our current knowledge and experience. In view of the many factors that may affect processing and application of our product, these data do not relieve processors from carrying out own investigations and tests; neither do these data imply any guarantee of certain properties, nor the suitability of the product for a specific purpose. Any descriptions, drawings, photographs, data, proportions, weights etc. given herein may change without prior information and do not constitute the agreed contractual quality of the product. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing laws and legislation are observed. (November 2024)

Further information on Ultraform® PRO (POM) and Ultradur® PRO (PBT)

www.medical-plastics.basf.com
www.ultraform.basf.com
www.ultradur.basf.com

Please visit our websites:

www.plastics.basf.com
www.plastics.basf.de

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