Engineering Plastics for Medical Solutions

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

Further information on individual products:

www.plasticsportal.eu/ultraform

www.ultradur.de

www.plasticsportal.eu/medical

BASF

We create chemistry

PRO – Engineering plastics for applications in medical technology

Increasing customer demands in sophisticated medical applications with high-performance profiles and long-term formulation consistency, prompted BASF to extend its portfolio of engineering plastics for medical technology.

BASF customers can reliably offer their products in this demanding market only if the formulation remains unchanged over a long-term period. This is especially important as the medical technology market is characterized by long development efforts and costly approval procedures. Materials that have demonstrated their reliability in comprehensive testing are essential for the production of safe drug delivery systems and other medical devices. This is why BASF's PRO products are an important link in the value chain – from the plastic raw material all the way to safe products for patients.

The PRO grades are adapted specifically for these requirements and needs of the medical technology industry. The suffix PRO (**P**rofile covered **R**aw materials **O**nly) expresses the claim that only very specific raw materials that are subject to strict controls are used. It points to an expanded service package for medical technology. The PRO service package offers evidence of and compliance with relevant stipulated international standards and tests regulating the use of plastics in medical and pharmaceutical applications.

All the materials covered in the PRO portfolio are in compliance with the regulations/recommendations or test requirements given in table 1 (approvals for natural or uncolored base materials respectively).

Table 1: Regulations/recommendations or test requirements that the PRO grades are in compliance with

Pharmaceutical and medical applications	• EU Pharmacopeia (EP 8th Edition, Chapter 3.2.2 "Plastic Containers and Closures for Pharmaceutical Use") basic requirements • Japanese Pharmacopeia (16th Edition, General Information, "G7 Plastic Containers for Pharmaceutical Products") basic requirements • US Pharmacopeia (USP Biological Reactivity Test Class VI) • Biocompatibility (Cytotoxicity according to ISO 10993-5) • Drug Master File (DMF)

Food contact applications	• Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food as amended
	• Commission Regulation (EU) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
	• 21 CFR Food Additive Regulations (FDA Compliance)
	  ◦ FDA Regulation 21 CFR § 177.2470 "Polyoxymethylene copolymer"
	  ◦ FDA Regulation 21 CFR § 177.1660 "Poly(tetramethylene terephthalate)"

Others	• Heavy Metals (CONEG (Coalition of North Eastern Governors) for the January 1, 1994, EU Directive 94/62/EEC on heavy metals, EU Directive 2000/53/EC on end-of life vehicles as amended • BSE/TSE Transmittance (no risk materials are used in the production, monomers/ingredients are of petro-chemical origin, additives from animal origin are in accordance with note for guidance EMEA/410/01 Rev. 03 adopted by the CPMP (Committee for Proprietary Medicinal Products) and CVMP (Committee for Veterinary Medicinal Products). In addition the treatment exceeds the requirements of the directive 2000/6/EG Annex II

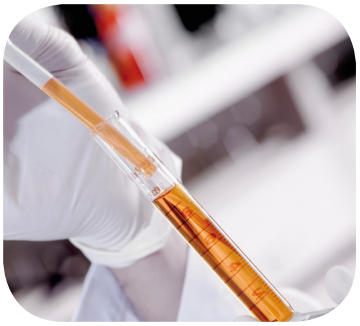
BASF offers, for example, preliminary experiments on chemical compatibility as well as biocompatibility tests, which are already performed on the pellets. Extraction studies conducted by independent external institutes also show the quality of the PRO grades. By supplying these certified plastics, BASF helps its customers to obtain approval for the final product and so supports long-term patient safety.

PRO Service Package – reliability and partnership in a demanding market

The extended PRO Service Package comprises:

- Documented intention not to change the plastic formulation (as lodged/defined in the Drug Master File DMF) in the long-term, except for necessary adjustments and external constraints respectively due to regulatory changes or amendments to general legal framework
- Guarantee to inform customers at least 36 months in advance of any unavoidable changes to resin formulations (as lodged/defined in the Drug Master File (DMF))
- Support of worldwide approvals for pharmaceutical and medical applications as well as for food contact
- Testing the compatibility of the plastic to specific chemicals
- Production conditions according to GMP (good manufacturing practices) principles Commission Regulation (EC) 2023/2006
- Application technology support (processing, design, calculation)

Ultraform® PRO (POM) – plastics for mechanical and tribological stress



Ultraform® (POM, polyoxymethylene) is a semi-crystalline copolymeric engineering plastic. Ultraform® is highly resistant to diverse chemicals. The good hydrolysis resistance as well as the dimensional stability under heat ensure that components made of Ultraform® are suitable for sterilization procedures like superheated steam, plasma and ethylene oxide. Products made of Ultraform® especially stand out for their smooth and hard surface. Moreover, Ultraform® can withstand mechanical stress very well and shows excellent friction and wear behavior. Due to the combination of outstanding resilience and sliding behavior Ultraform® is highly suitable for the production of functional components such as valves, plugin connectors, gearwheels and spring elements.

The six Ultraform® PRO grades show a wide range of flowability (from 2.2 to 25 cm³/10 min), covering the requirements for extrusion (stock shapes) and injection molding from thick-walled parts up to thinwalled parts with long flow paths.

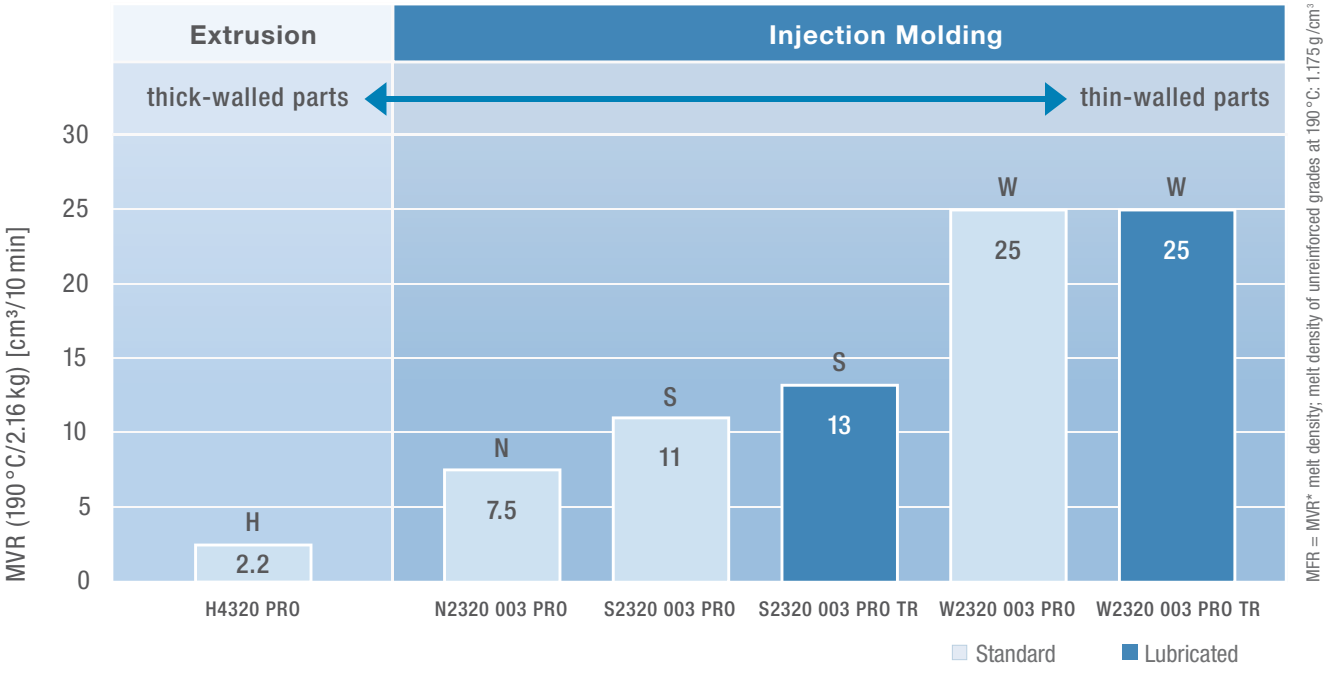


Fig. 1: Availability of Ultraform® PRO: first letter indicates melt viscosity (MVR)

Ultraform® S2320 003 PRO is a standard flowing and rapidly freezing grade suitable for standard functional applications. In contrast, Ultraform® W2320 003 PRO is a very easy flowing grade for thin-walled components with long flow paths. Both Ultraform® S2320 003 PRO and Ultraform® W2320 003 PRO are predestined for components where high stiffness and simultaneously an outstanding resilience are required. Ultraform® S2320 003 PRO TR and Ultraform® W2320 003 PRO TR are injection molding grades with good flowability, including a special lubricant to minimize squeaking and slick-slip.

Ultraform® N2320 003 PRO is a rapidly solidifying grade with enhanced viscosity. It is well suited for the production of thick-walled components requiring high mechanical strength due to its excellent impact resistance and stiffness.

The Ultraform® N, S and W PRO grades for injection molding are suited for the manufacturing of functional components in insulin pens, atomizing devices and dry-powder inhalers.

Ultraform® H4320 PRO has been tailored specifically for extrusion processes. It has even higher viscosity than the Ultraform® N grade and is more impact-resistant while also being very stiff as well as strong. It also shows good thermal stability. Its target applications are plug-in connectors, the handles of surgical instruments and other components in small production runs that are made form semi-finished parts.

Table 2: Ultraform® PRO at a glance

Properties	Possible applications	Processing
• High crystallinity • Ideal combination of strength, stiffness and toughness • Outstanding tribological properties, i. e. low friction and wear, very good sliding properties • Excellent long-term behavior, low fatigue under mechanical stress • Very good resilience • Excellent chemical and hydrolysis resistance • Withstands sterilization with hot-steam, plasma and ethylene oxide • Excellent thermal and oxidative stability, high resistance to heat deflection (continuous temperatures of up to 100 °C) • Good processability	• Functional and mechanical components with high dimensional precision and stability for use in medical devices such as insulin pens, inhalers or atomising systems • Device components such as spring elements, snap-fits, gearwheels, bearings, sleeves, valves or nozzles • Tribological systems such as cylinders, screws, sliders or nuts • Clamps for inner tubes, clips or plug-in connectors • Pharmaceutical closures • Handles for surgical instruments • Transmission and connecting elements for conveyor chains and belts	• Injection Molding • Extrusion

Ultradur® PRO (PBT) – plastics for high precision requirements and dimensional stability

BASF Ultradur® (PBT, polybutylene terephthalate) is a semi-crystalline engineering plastic, which is part of the polyester family of resins. Among the many features of Ultradur® are outstanding mechanical properties like rigidity and strength combined with excellent heat aging behavior. Depending on the friction partner, Ultradur® shows excellent sliding behavior. Ultradur® can be easily processed by injection molding due to its good flow properties. Short cycle times can be achieved.

Ultradur® B4520 PRO is suited for injection molding applications in medical technology. The Ultradur® B4520 PRO grade offers the combination of high dimensional stability with a uniform shrinkage behavior. Products made from Ultradur® B4520 PRO are able to meet the strict requirements of dimensional component accuracy intended for medical devices. Other advantages of this material are low water absorption under standard use conditions for medical devices as well as high resistance to many chemicals. Ultradur® B4520 PRO can be easily printed using hot stamping as well as pad printing processes and sterilised with ionizing (gamma) radiation or ethylene oxide. Ultradur® B4520 PRO TR is a new tribological grade with improved friction, sliding and wear properties.

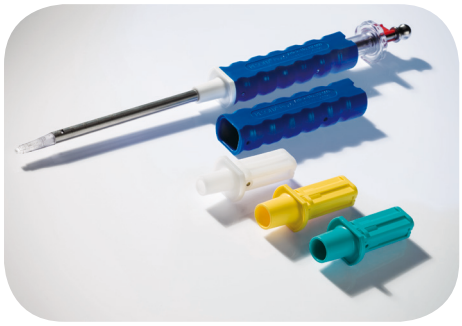


Table 3: Ultradur® PRO at a glance

Properties	Possible applications	Processing
• High reproducibility accuracy plus high dimensional stability due to improved shrinking behavior • Broad chemical resistance to polar and non-polar solvents • Low water/moisture absorption • Ideal sliding, due to high friction and wear resistance (depending on the sliding partner) • Very good printability (can be decorated using the hot stamping and pad printing processes) • Excellent heat aging behavior • Retains its property profile on exposure to ionizing radiation and ethylene oxide • Good moldability with fast cycles	• Functional and mechanical components with high dimensional precision and stability for use in drug delivery systems such as insulin pens, inhalers or metering devices • Device components such as manifolds, screws, sleeves, valves, plungers, lancets or caps • Chassis and housings • Filter systems • Drug containers • Pharmaceutical closures • Technical disposable applications	• Injection Molding • Extrusion

PRO grades for tribologically stressed functional parts

Tribological pairing of components made of Ultraform® PRO and Ultradur® PRO offers additional benefits. For instance, insulin pens with excellent sliding friction properties can be produced in combination with these materials. Ultraform® is making a contribution to lower the friction between the contacting functional parts, and Ultradur® is acting as a slip/sliding partner reducing annoying noises during operation.

Good results in terms of friction, wear resistance and reduced noise emissions will also be achieved with the combination of Ultradur® B4520 PRO and every Ultraform® PRO grade.

Further material properties

All materials used in medical technology must meet specific purification requirements regarding chemical resistance and resistance to sterilisation. The figures 2 and 3 give an overview about the resistance against typical cleaning additives and purification methods.

Fig. 2: Long-term chemical resistance of Ultraform® PRO and Ultradur® PRO

	Aliphatic hydrocarbons	Aromatic hydrocarbons	Alkaline aqueous solutions	Ethers	Esters	Aliphatic alcohols	Water & aqueous solutions	Organic acids	Ketones
Ultraform® PRO (POM)	+	+	+[2]	+	+	+[4]	+[6]	o[8]	+
Ultradur® PRO (PBT)	+	+[1]	o[3]	+	+	+[5]	o[7]	+	+

1 limited resistance: possible strong swelling at elevated temperatures

2 limited resistance: soda lye, ammonia water, carbamide solution, amine

3 limited resistance: weakly alkaline media: carbamide solution, soda lye pH 10
non-resistant: strongly alkaline media: soda lye pH 14

4 limited resistance: >60 °C ethanol, methanol & isopropanol

5 limited resistance: >40 °C ethanol, methanol & isopropanol

6 limited resistance: chlorinated drinking water, acidic/oxidising solutions

7 limited resistance: 40-90 °C (humidity)
non-resistant: >90 °C (humidity)

8 limited resistance: aqueous dilution → acetic acid, formic acid, citric acid, benzoic acid

+ = resistant o = limited resistance

Fig. 3: Resistance to sterilisation of Ultraform® PRO and Ultradur® PRO

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

+ = resistant o = limited resistance - = non-resistant
*Superheated steam resistance is dependent on conditions → duration and number of cycles

Annotation

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.

However, BASF has not designed or tested its plastics with respect to all of the special requirements related to their use in medical devices (defined in risk classes I to III according to the European and US Medical Device legislation) and pharmaceutical applications. Therefore BASF makes no warranties, express or implied, concerning the suitability of any BASF plastics for use in any medical device and pharmaceutical applications. Please inform us in advance, if you intend to use BASF plastics in medical devices or pharmaceutical applications.

BASF does not supply its plastics for the manufacture of implants in any risk class. BASF expressively advises against plastics supplied for other purposes being used for these medical applications.

Subject to an evaluation and a release in each individual case BASF is prepared to supply plastics for medical applications within risk class I or for pharmaceutical applications such as solid dosage forms for oral applications. Provided an agreement can be reached which takes into account the circumstances of each individual case and a disclaimer is accepted by the customer BASF is prepared to supply plastics for individual medical applications within risk class II (with the exception of implants) including packaging of parenteral and ophthalmic products as well as inhalers.

Should a customer wish to use BASF plastics in applications within risk class III, which are not implants, sale is possible only in very exceptional cases at the special request of the customer. However, a detailed risk assessment has to be provided.

In all cases the BASF customer has to establish from their own experience and from tests on BASF plastics, that these plastics are suitable for the manufacture of products for medical applications or pharmaceutical applications (with the exception of implants) including packaging of parenteral and ophthalmic products as well as inhalers. The customer has also to ensure that the medical device or pharmaceutical application manufactured using BASF plastics is safe, lawful and technically suitable for the intended use.

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

Typical values for uncolored products at 23 °C	Unit	Test method	Ultraform® H4320 PRO	Ultraform® N2320 003 PRO
Properties				
Polymer abbreviation	–	–	POM	POM
Density	kg/m³	ISO 1183	1,390	1,400
Melt volume rate MVR*	cm³/10 min	ISO 1133	2.2	7.5
Melt flow rate MFR (190 °C/2.16 kg)	g/10 min		2.6	8.8
Reinforcing material	–	–	without	without
Water absorption, equilibrium in water at 23 °C	%	similar to ISO 62	0.8	0.8
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, E	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	2.2	2.1
Molding shrinkage (normal)	%	ISO 2577, 294-4	2.1	2.1
Mechanical Properties				
Tensile modulus	MPa	ISO 527-1/-2	2,600	2,700
Yield stress, 50 mm/min	MPa	ISO 527-1/-2	63	65
Yield strain, 50 mm/min	%	ISO 527-1/-2	10	9.4
Nominal strain at break, 50 mm/min	%	ISO 527-1/-2	31	27
Tensile creep modulus (1h)	MPa	ISO 899-1	1,800	1,800
Tensile creep modulus (1,000 h)	MPa	ISO 899-1	1,300	1,400
Charpy unnotched impact strength (23 °C)	kJ/m²	ISO 179/1eU	250	210
Charpy unnotched impact strength (-30 °C)	kJ/m²	ISO 179/1eU	180	190
Charpy notched impact strength (23 °C)	kJ/m²	ISO 179/1eU	6	6
Charpy notched impact strength (-30 °C)	kJ/m²	ISO 179/1eU	5.5	5.5
Ball indentation hardness at 358 N and 30 s	MPa	ISO 2039-1	125	145
Thermal Properties				
Melting temperature, DSC (20 °C/min)	°C	ISO 11357-1/-3	166	167
HDT A (1.80 MPa)	°C	ISO 75-1/-2	95	100
HDT B (0.45 MPa)	°C	ISO 75-1/-2	155	156
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	120	110
Compliance – pharmaceutical/medical				
USP Class VI			Yes	Yes
Cytotoxicity (ISO 10993-5)			Yes	Yes
Drug Master File (DMF)			24606	24607
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.

*** Melt temperature, extrusion: 175-180 °C

Ultraform® S2320 003 PRO	Ultraform® S2320 003 PRO TR	Ultraform® W2320 003 PRO	Ultraform® W2320 003 PRO TR	Ultradur® B4520 PRO	Ultradur® B4520 PRO TR
POM	POM	POM	POM	PBT	PBT
1,400	1,400	1,400	1,370	1,300	1,300
11	13	25	25	25	21
13	–	29.4	29	–	–
without	without	without	without	without	without
0.8	0.8	0.8	0.8	0.5	0.5
0.2	0.2	0.2	0.2	0.25	0.25
M	M	M	M	M, (E)	M, (E)
100**	100**	100**	100**	80 - 120	80 - 120
3**	3**	3**	3**	4	4
0.2**	0.2**	0.2**	0.2**	0.04	0.04
190 - 230	190 - 230	190 - 230	190 - 230	250 - 270	250 - 270
60 - 120	60 - 120	60 - 120	60 - 120	40 - 70	40 - 70
2.1	2.2	2.0	2.1	2.1	2.1
2.1	2.0	2.1	2.1	2.5	2.5
2,700	2,600	2,800	2,500	2,600	2,600
65	62	65	50	60	55
9	9	7.5	5	10.8	3.3
28	35	24	35	30	30
1,900	–	2,100	1,850	1,800	–
1,300	–	1,350	1,100	1,200	–
180	180	150	100	228	184
170	145	150	110	140	168
5.5	5.5	5	4	4.5	3.6
5	6	4	4	3	4
145	–	145	125	130	120
167	167	167	167	223	223
100	100	100	90	55	58
156	–	156	–	165	145
150	–	150	–	–	–
100	100	100	90	200	200
110	120	110	125	145	–
Yes	Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes	Yes
19888	26560	19889	26560	24605	–
Yes	Yes	Yes	Yes	Yes	Yes
§ 177.2470	§ 177.2470	§ 177.2470	§ 177.2470	§ 177.1660	§ 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 2015)

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