Ultraform® N2320 003 PRO AT

POM BASF

Rapidly solidifying standard grade for injection molding.

Ultraform® PRO offers a comprehensive service package, which supports customers in product development for the medical technology market.

Ultraform® PRO complies with the basic requirements of Pharmacopoeia and Biocompatibility-Tests in Europe, United States and Japan respectively as specified below. However, the biocompatibility tests were recorded on tests specimens of Ultraform PRO to show compatibility and potential suitability of the material in general. The biocompatibility-tests and the other tests listed below are not part of any continuous production control.

European Pharmacopoeia, Japanese Pharmacopoeia:
The composition of the product complies with the basic requirements of the European Pharmacopoeia 8th Edition, Chap. 3.2.2. "Plastic Containers and Closures for Pharmaceutical Use" and with the basic requirements of the Japanese Pharmacopoeia,16th Edition, General Information, “17. Plastic Containers for Pharmaceutical Products”. However, suitability for the end application concerned including observation of given limitations and toxicological thresholds have to be ensured on the final article by the producer.

US Pharmacopoeia: Biological Reactivity Tests, USP Plastic Class VI (USP VI)

ISO 10993-5: Biological Evaluation of Medical Devices Part 5: Test for Cytotoxicity

DMF: A Drug Master File (DMF) has been registered at FDA for Ultraform® PRO.

Food Contact: Ultraform® PRO is in compliance with multiple regional food contact regulations, especially for Europe and United States.

Additional compliances may also be available. Please contact your local representative or the Ultraplaste Infopoint (E-Mail: ultraplaste.infopoint@basf.com, Telefon: 49 621-60-78780, Fax: 49 621-60-78730).

For notice:
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.

Abbreviated designation according to ISO 1043-1: POM
Designation according to ISO 29988-POM-K,,M-GNR,4-2

Rheological properties	Value	Unit	Test Standard
ISO Data			
Melt volume-flow rate, MVR	7.5	cm³/10min	ISO 1133
Temperature	190	°C	-
Load	2.16	kg	-
Molding shrinkage, parallel	2.1	%	ISO 294-4, 2577
Molding shrinkage, normal	2.1	%	ISO 294-4, 2577

Mechanical Properties	Value	Unit	Test Standard
ISO Data			
Tensile Modulus	2700	MPa	ISO 527
Yield stress	64	MPa	ISO 527
Yield strain	10.7	%	ISO 527
Nominal strain at break	32	%	ISO 527
Tensile Creep Modulus, 1h	1800	MPa	ISO 899-1
Tensile Creep Modulus, 1000h	1400	MPa	ISO 899-1
Impact Strength (Charpy), +23°C	270	kJ/m²	ISO 179/1eU
Impact Strength (Charpy), -30°C	250	kJ/m²	ISO 179/1eU
Notched Impact Strength (Charpy), +23°C	6.5	kJ/m²	ISO 179/1eA
Notched Impact Strength (Charpy), -30°C	5.5	kJ/m²	ISO 179/1eA

Thermal Properties	Value	Unit	Test Standard
ISO Data			
Melting Temperature (10°C/min)	166	°C	ISO 11357-1/-3
Temp. of deflection under load (1.80 MPa)	95	°C	ISO 75-1/-2
Temp. of deflection under load (0.45 MPa)	156	°C	ISO 75-1/-2

Ultraform® N2320 003 PRO AT

POM BASF

Vicat softening temperature, 50°C/h 50N	150	°C	ISO 306
Coeff. of Linear Therm. Expansion, parallel	110	E-6/K	ISO 11359-1/-2
Burning Behav. at 1.5 mm Nom. Thickn.	HB	class	UL 94
Thickness tested	1.6	mm	-
UL recognition	yes	-	-
Burning Behav. at thickness h	HB	class	UL 94
Thickness tested	0.8	mm	-
UL recognition	yes	-	-
Oxygen index	15	%	ISO 4589-1/-2

Electrical Properties	Value	Unit	Test Standard
ISO Data			
Relative permittivity, 100Hz	3.8	-	IEC 62631-2-1
Relative permittivity, 1MHz	3.8	-	IEC 62631-2-1
Dissipation Factor, 100Hz	10	E-4	IEC 62631-2-1
Dissipation Factor, 1MHz	50	E-4	IEC 62631-2-1
Volume Resistivity	1E11	Ohm*m	IEC 62631-3-1
Surface Resistivity	1E13	Ohm	IEC 62631-3-2
Electric Strength	40	kV/mm	IEC 60243-1
Comparative tracking index	600	-	IEC 60112

Other Properties	Value	Unit	Test Standard
ISO Data			
Water Absorption	0.9	%	Sim. to ISO 62
Humidity absorption	0.2	%	Sim. to ISO 62
Density	1410	kg/m³	ISO 1183

Rheological calculation properties	Value	Unit	Test Standard
ISO Data			
Ejection temperature	110	°C	-

Test specimen production	Value	Unit	Test Standard
ISO Data			
Injection Molding, melt temperature	200	°C	ISO 294
Injection Molding, mold temperature	90	°C	ISO 294
Injection Molding, injection velocity	200	mm/s	ISO 294

Processing Recommendation Injection Molding	Value	Unit	Test Standard
Pre-drying - Temperature	100	°C	-
Pre-drying - Time	3	h	-
Processing humidity	≤0.2	%	-
Melt temperature	190 - 230	°C	-
Mold temperature	60 - 120	°C	-

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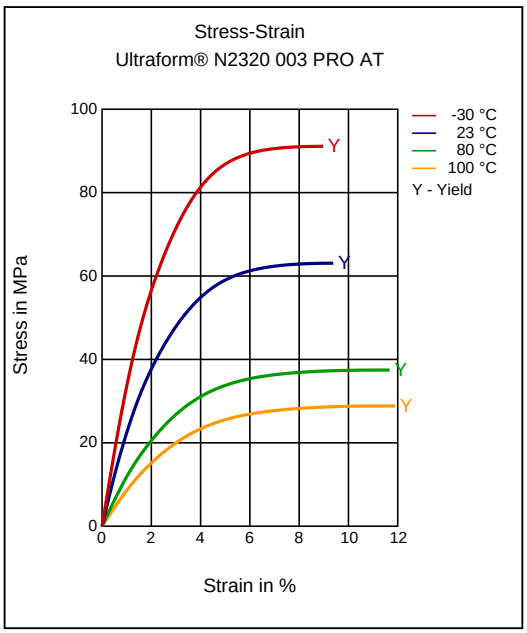
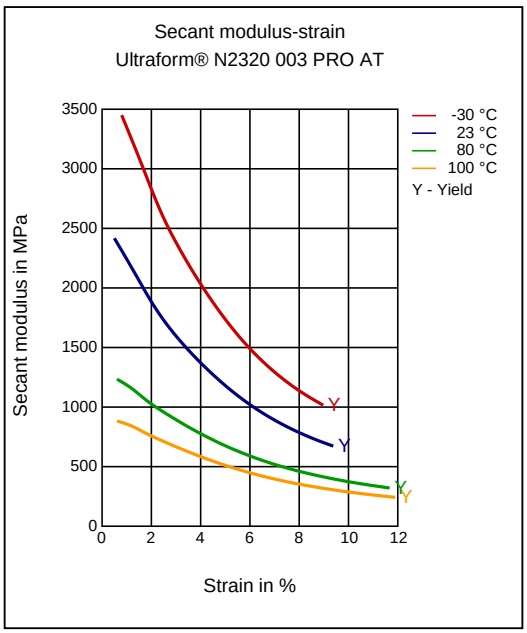
Diagrams

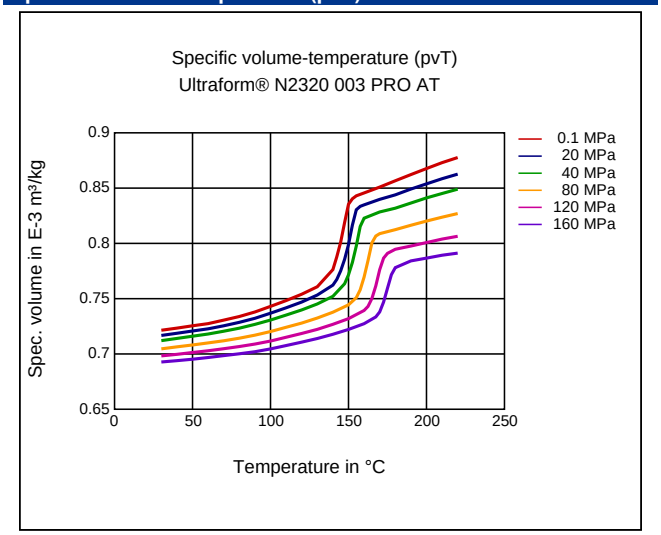
Stress-strain



Secant modulus-strain



Specific volume-temperature (pvT)



Characteristics

Processing

Injection Molding

Delivery form

Pellets

Additives

Release agent

Certifications

Medical, Biocompatibility ISO 10993, US Pharmacopeia Class VI Approved, Drug Master File, Food approval

Applications

Medical

Injection Molding

PREPROCESSING

Pre/Post-processing, max. allowed water content: .2 %

Pre/Post-processing, Pre-drying, Temperature: 100 °C
Pre/Post-processing, Pre-drying, Time: 3 h

PROCESSING
injection molding, Melt temperature, range: 190 - 230 °C
injection molding, Melt temperature, recommended: 200 °C
injection molding, Mold temperature, range: 60 - 120 °C
injection molding, Mold temperature, recommended: 90 °C
injection molding, Dwell time, thermoplastics: 10 min

Processing

Usual single-flighted three-section screws with an effective screw length of at least 15 D, better 20 - 23 D are suitable for the injection molding of Ultraform.

Pretreatment

Granules or pellets in original packaging can be processed without any special pretreatment. 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 recirculating air dryers for approx. 3 hours at about 100 - 110 °C. The moisture content should not exceed 0.2 %.

Postprocessing

If parts were produced at a comparatively low mold temperature (e.g. in order to obtain short cycle times) and must not change their geometry in use thermal postprocessing inducing dimensional changes by postcrystallization may be necessary. In such cases parts should be stored in an oven with recirculated air at temperatures of 100 - 130 °C until dimensions don't change significantly any further. The time needed for this has to be determined experimentally.