

Ultraform® S1320 003 PRO AT POM

BASF

Free-flowing, rapidly solidifying grade for moldings difficult to produce by injection molding and having low wall thickness; increased stiffness and heat distortion resistance.

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

流变性能	数值	单位	试验方法
ISO数据			
熔体体积流动速度, MVR	11	cm ³ /10min	ISO 1133
温度	190	°C	-
载荷	2.16	kg	-
模塑收缩率, 平行	2.1	%	ISO 294-4, 2577
模塑收缩率, 垂直	2.1	%	ISO 294-4, 2577

机械性能	数值	单位	试验方法
ISO数据			
拉伸模量	3000	MPa	ISO 527
屈服应力	67	MPa	ISO 527
屈服伸长率	10.5	%	ISO 527
名义断裂伸长率	25	%	ISO 527
拉伸蠕变模量, 1000h	1450	MPa	ISO 899-1
无缺口简支梁冲击强度, +23°C	230	kJ/m ²	ISO 179/1eU
无缺口简支梁冲击强度, -30°C	210	kJ/m ²	ISO 179/1eU
简支梁缺口冲击强度, +23°C	6	kJ/m ²	ISO 179/1eA
简支梁缺口冲击强度, -30°C	5.5	kJ/m ²	ISO 179/1eA

热性能	数值	单位	试验方法
ISO数据			
熔融温度, 10°C/min	170	°C	ISO 11357-1/-3
热变形温度, 1.80 MPa	100	°C	ISO 75-1/-2
热变形温度, 0.45 MPa	159	°C	ISO 75-1/-2

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维卡软化温度, 50°C/h 50N	150	°C	ISO 306
线性热膨胀系数, 平行	110	E-6/K	ISO 11359-1/-2
1.5mm名义厚度时的燃烧性	HB	class	UL 94
测试用试样的厚度	1.6	mm	-
UL注册	是的	-	-
厚度为h时的燃烧性	HB	class	UL 94
测试用试样的厚度	0.8	mm	-
UL注册	是的	-	-
燃烧性 - 氧指数	15	%	ISO 4589-1/-2

电性能	数值	单位	试验方法
ISO数据			
相对介电常数, 100Hz	3.7	-	IEC 62631-2-1
相对介电常数, 1MHz	3.7	-	IEC 62631-2-1
介质损耗因子, 100Hz	20	E-4	IEC 62631-2-1
介质损耗因子, 1MHz	50	E-4	IEC 62631-2-1
体积电阻率	1E11	Ohm*m	IEC 62631-3-1
表面电阻率	1E15	Ohm	IEC 62631-3-2
介电强度	40	kV/mm	IEC 60243-1
相对漏电起痕指数	600	-	IEC 60112

其它性能	数值	单位	试验方法
ISO数据			
吸水性	0.9	%	类似ISO 62
吸湿性	0.2	%	类似ISO 62
密度	1410	kg/m³	ISO 1183

流变计算用参数	数值	单位	试验方法
ISO数据			
喷射温度	110	°C	-

试样制备条件	数值	单位	试验方法
ISO数据			
注塑, 熔体温度	200	°C	ISO 294
注塑, 模具温度	90	°C	ISO 294
注塑, 注射速度	200	mm/s	ISO 294

加工推荐 (注塑)	数值	单位	试验方法
预干燥-温度	100	°C	-
预干燥-时间	3	h	-
加工湿度	≤ 0.2	%	-
注塑熔体温度	190 - 230	°C	-
模具温度	60 - 120	°C	-

特征

加工方法

注塑

供货形式

粒料

添加剂

脱模助剂

生态估价

医用级, Biocompatibility ISO 10993, US药物六级认证, Drug Master File, 食物接触声明

应用

药物

注塑

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.

权利义的法律声明

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医疗保健方面的应用: 本公司在向客户供应医用，药用及用于诊断的医疗产品之前，必须依据本公司内部所定风险管理准则对其应用做出评估，即便此产品在常规上已被视作适用于医疗保健方面的应用。

重要 - 本公司原则上拒绝以下所有医用，药用或用于诊断的医疗产品

- 依据欧盟医疗器械指令EU directive 93/42/EEC 被划分为危险等级3的医疗产品

- 移入体内的并且在体内停留时间超过30天的医疗产品

- 用于医疗器械的具有维持生命或延长生命的关键部件

请注意，本公司通用销售及交货条款在任何时间均有效。