Processing Data Sheet **Ultraform®**

W2320 003 PRO AT

11/2022

POM

Product description

Very free-flowing, rapidly solidifying grade for use where processing is extremely difficult but mechanical properties are lower.

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,5-2

Physical form and storage

Ultraform® is supplied in the form of granules having a bulk density of approx. 850 g/l. Standard packs are 25 kg PE bag and 1000 kg Octabin (octagonal container). Ultraform® is not subject to change when it is stored in dry, ventilated rooms. After relatively long storage (>1 year) or when handling material from previously opened containers, preliminary drying is recommended in order to remove any moisture which has been absorbed.

Product safety

Ultraform® is not a hazardous material as defined in the German Ordinance on Hazardous Materials.

If Ultraform® is processed properly little or no formaldehyde occurs in the region of the processing machine. Measures should be taken to ensure ventilation and venting of the work area, preferably by means of an extraction hood over the barrel unit.

Ultraform® decomposes when subjected to excessive heat. The decomposition products formed in this case consist almost exclusively of formaldehyde, a gas which has a pungent smell even at very low concentrations and irritates the mucous membranes. Decomposition can rapidly result in the build-up of a high gas pressure in the barrel of the processing unit. If the die is sealed there may be a sudden release of pressure via the filling hopper.

Contamination of Ultraform® by thermoplastics that cause decomposition of polyacetals, e.g. PVC or plastics containing halogenated fire protection agents, must be avoided under all circumstances. Even small quantities can cause uncontrolled and rapid decomposition of Ultraform® during processing.

If processing with color masterbatches or functional batches is intended, the compatibility of the components must be established by suitable trials. Processing with incompatible masterbatches may result in decomposition and release of gaseous formaldehyde.

Pellets and finished parts must not be allowed to come into contact with strong acids (especially concentrated hydrochloric acid) since they cause Ultraform® to decompose.

Detailed safety and environmental information is contained in the Ultraform® brochure and the material safety data sheet.

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67056 Ludwigshafen, Germany

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Both are available from the PlasticsPortal, www.plasticsportal.net, or the Ultra-Infopoint under phone +49-621-60-78780 or fax +49-621-60-78730.

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 their 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.
In order to check the availability of products please contact us or our sales agency.

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We create chemistry

	Test method	Unit	Values
Properties			
Polymer abbreviation	-	-	**POM**
Density	ISO 1183	kg/m³	**1410**
Melt volume rate MVR 190 °C/2.16 kg	ISO 1133	cm³/10min	**25**
Drying			
Moisture, max.	-	%	**0.2**
Dryer temperature [1)]	-	°C	**100**
Drying time	-	h	**3**
Injection molding			
Melt temperature range	-	°C	**190 - 230**
Melt temperature, optimal	-	°C	**200**
Mold temperature range	-	°C	**60 - 120**
Mold temperature, optimal	-	°C	**90**
Residence time, max.	-	min	**10**
Machine Settings			
Temperature hopper throat	-	°C	**80**
Cylinder temperature 1 (feed zone)	-	°C	**200**
Cylinder temperature 2 (compression)	-	°C	**200**
Cylinder temperature 3 (metering-zone, in front of the screw)	-	°C	**200**
Cylinder temperature 4 (nozzle)	-	°C	**200**
Peripheral screw speed	-	m/s	**0.3**
Shrinkage			
Molding shrinkage (parallel)	ISO 294-4	%	**2.00**
Molding shrinkage (normal)	ISO 294-4	%	**2.10**

Footnotes

1) The granules or pellets in their original packaging can generally be processed without any special preliminary treatment. However, granules or pellets which have become moist due to prolonged or incorrect storage must be dried in suitable dryers, e.g. dehumidifying dryers.

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