Preliminary

Processing Data Sheet

Ultradur®

B 4521 PRO

11/2022

PBT

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Product description

Ultradur® PRO offers a comprehensive service package, which supports customers in product development for the medical technology market.
Ultradur® PRO is in compliance with Pharmacopoeia and Biocompatibility-Tests in Europe, United States and Japan as specified below. However, the biocompatibility tests were recorded on tests specimens of Ultradur PRO to show compatibility of the material in general. The biocompatibility-tests listed below are not part of any continuous production control.
European Pharmacopoeia, Japanese Pharmacopoeia:
The composition of the product complies with the requirements of the European Pharmacopoeia 7th Edition, Chap. 3.2.2. "Plastic Containers and Closures for Pharmaceutical Use" and with the requirements of the Japanese Pharmacopoeia, 15th 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 Ultradur® PRO.

Food Contact: Ultradur® 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, telephone: +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: PBT

Product safety

Ultradur® melts are stable at temperatures up to 280°C and do not give rise to hazards due to molecular degradation or the evolution of gases and vapors. Like all thermoplastic polymers, however, Ultradur decomposes on exposure to excessive thermal stresses, e.g. when it is overheated or as a result of cleaning by burning off. At temperatures of > 290 °C can be emitted: carbon monoxide, tetrahydrofuran.
Under special fire conditions traces of other toxic substances are possible. Formation of further decomposition and oxidation products depends upon the fire conditions.
When Ultradur® is properly processed and there is adequate suction at the die no risks to health are to be expected.
Further safety information see safety data sheet of individual product.
Safety data sheet could be ask for at the Ultra-Infopoint under tel: 0621/60-78780 or fax:0621/60-78730.

Physical form and storage

Standard packaging includes the 25-kg-bag and the 1000 kg octabin (octagonal container). Other forms of packaging are possible subject to agreement. All containers are tightly sealed and should be opened only immediately prior to processing. Further precautions for preliminary treatment and drying are described in the processing section of the brochure. The bulk density is about 0,7 to 0,8g/cm³.
Ultradur® can be stored for a longer period of time in dry, well vented rooms without causing problems in processing.
Ultradur® should generally have a moisture content of less than 0,04% when being processed.
In order to ensure reliable production, therefore, pre-drying should generally be the rule and the machine should be loaded via a closed conveyor system. Appropriate equipment is commercially available. Pre-drying is also for the addition of batches, e.g. in the case of inhouse pigmentation.
In order to prevent the formation of condensed water, containers stored in unheated rooms must only be opened when they have attained the temperature prevailing in the processing area. This can possibly take a very long time.
Measurements have shown that the interior of a 25-kg bag originally at 5°C had reached the temperature of 20°C in the processing area only after 48 hours.

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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	Test method	Unit	Values
Properties			
Polymer abbreviation	-	-	**PBT**
Density	ISO 1183	kg/m³	**1300**
Melt volume rate MVR 250 °C/2.16 kg	ISO 1133	cm³/10min	**25**
Drying			
Moisture, max.	-	%	**0.04**
Dryer temperature [1)]	-	°C	**80 - 120**
Drying time	-	h	**4**
Injection molding			
Melt temperature range	-	°C	**250 - 270**
Melt temperature, optimal	-	°C	**260**
Mold temperature range	-	°C	**40 - 70**
Mold temperature, optimal	-	°C	**60**
Machine Settings			
Temperature hopper throat	-	°C	**80**
Cylinder temperature 1 (feed zone)	-	°C	**250**
Cylinder temperature 2 (compression)	-	°C	**255**
Cylinder temperature 3 (metering-zone, in front of the screw)	-	°C	**260**
Cylinder temperature 4 (nozzle)	-	°C	**260**
Peripheral screw speed	-	m/s	**0.25**
Shrinkage			
Molding shrinkage (parallel)	ISO 294-4	%	**2.10**
Molding shrinkage (normal)	ISO 294-4	%	**2.50**

Footnotes
1) Dry air dryer or vacuum dryer

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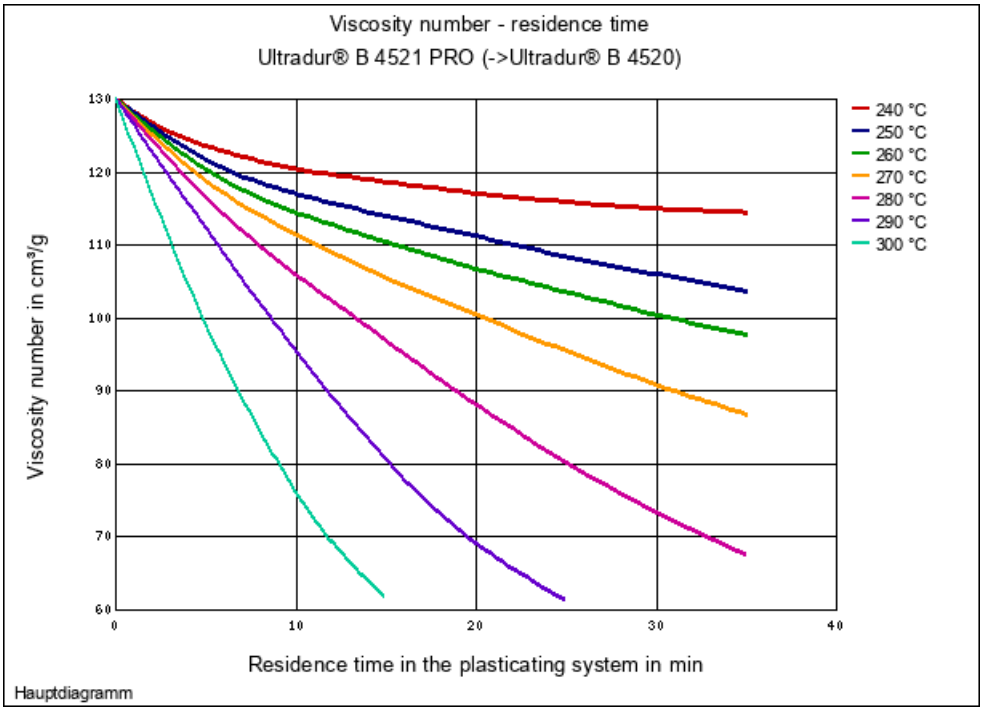
VISCOSITY NUMBER - RESIDENCE TIME



Unnecessarily high melt temperatures and excessively long residence times of the melt in the cylinder and the hot runner can bring about molecular degradation.
The figure shows an example (Ultradur® B4520) illustrating how the viscosity number acts as a measure of the molecular weight as a function of the melt temperature and residence time. Based on experience material degradation of less than 10 % based on the measured viscosity in solution of the granules and the molding is tolerable. In the event of values higher than this the processing and drying parameters should be checked.

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