Product Information

02/2007

Terlux[®] 2802 HD

MABS

The Chemical Company

Product description

Terlux® 2802 HD is an easily processable thermoplastic based on an MABS polymer, which offers an excellent combination of high transparency, good mechanical strength and rigidity as well as an excellent chemical and stress cracking resistance. Terlux® 2802 HD is in compliance with Pharmacopoeia and Biocompatibility-Tests in Europe and United States as

specified below.

However, the biocompatibility tests were recorded on tests specimens of TERLUX® 2802 HD to show compatibility of the material in general. The biocompatibility-tests listed below are not part of any continuous production control European Pharmacopoeia:

The composition of the product complies with the requirements of the European Pharmacopoeia 5th Edition, Chap. 3.2.2. "Plastic Containers and Closures".

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 Terlux® 2802 HD. The assigned DMF Number is 18074.

Physical form and storage

Terlux® is supplied as lenticular and as cylindrical pellets. The bulk density is from about 0.55-0.65 g/cm3. Standard pack: 25 kg PE sack, palletized and film-secured. Subject to agreement, other means of packing are possible, e.g. 1000 kg bulk containers (octagonal IBCs, or intermediate bulk containers, made from corrugated board with sack insert) or shipping by road tanker can be arranged. Terlux® pellets can be stored for prolonged periods in dry areas subject to normal temperature control without any changes in mechanical properties. However, with sensitive colors storage over some years can cause some color change. In poor storage conditions, Terlux® absorbs moisture, which can be removed again by drying. Packs stored in cold areas should be brought to ambient temperature before opening to prevent condensation on the pellets.

Product safety

Given appropriate processing of the products and suitable ventilation measures in production areas, no adverse effects on the health of process operator have been found. Workplace limits for styrene, methyl methacrylate, methyl acrylate,

the nearth of process operator have been found. Workplace limits for styrene, methyl methactylate, methyl acrylate, acrylonitrile and 1,3-butadiene, as given in the national listings applicable, must be adhered to. The values currently applicable in Germany under TRGS 900 (issue of September, 1999) for maximum workplace concentrations are as follows. Styrene: 20 ml/m3 = 85 mg/m3; methyl methacrylate: 50 ml/m3 = 210 mg/m3; methyl acrylate: 5 ml/m3 = 18 mg/m3; acrylonitrile: 3 ml/m3 = 7 mg/m3; 1,3-butadiene; 5 ml/m3 = 11 mg/m3. Appendix I of Directive 67/548/EWG (issue of 1999) classifies acrylonitrile and 1,3-butadiene in carcinogenic category II (substances which should be regarded as carcinogenic in humans).

Experience has shown that during appropriate processing of Terlux with suitable ventilation the values obtained are well below the limits mentioned above. TRGS 402 (Germany) can be used for determining and assessing the concentrations of hazardous substances in the air within working areas.

Inhalation of gaseous degradation products, such as those which may arise on severe overheating of the material or during pumped evacuation, must be avoided. Further information can be found in our Terlux safety data sheets. These can be downloaded from the Plastics Portal, www.plasticsportal.net.

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 processor from carrying out own investigations and tests neither do these data imply any guarantee for certain properties nor the suitability of the product for a specific purpose; therefore, the decision on the use of BASF plastics for a specific application is solely at our customer own risk.

BASF has not developed its plastics especially for the use in medical devices within the meaning of European Medical Devices legislation, such as medical applications involving (short-term) body contact or (temporary) implantation in the human body, or involving (short-term or temporary) contact with fluids and tissues present in the body or intro duced into the body, including packaging of parenteral and ophthalmic products. Therefore BASF does not claim suitability for any specific medical application. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that the medical device manufactured using BASF plastics is safe and technically suitable for the intended use. Moreover, BASF does never supply its plastics for the manufacture of implants.

Any descriptions, drawings, photographies, data, proportions, weights etc. given herein may change without prior information and do not constitute an agreed contractual quality of the plastics. It is the responsibility of the recipient of our plastics to ensure that any proprietary rights and existing laws and legislation are observed.

Terlux® 2802 HD

Typical values at 23°C ¹⁾	Test method ²⁾	Unit	Values ³⁾
Properties			
Polymer abbreviation Density Water absorption, equilibrium in water at 23°C Moisture absorption, equilibrium 23°C/50% r.h. Refractive index, crystal clear and transparent	ISO 1183 similar to ISO 62 similar to ISO 62 ISO 489	- kg/m³ % -	MABS 1080 0.7 0.35 1.540
Processing			
Melt volume-flow rate MVR Temperature Load Melt volume-flow rate MVR Temperature Load Melt temperature, injection moulding Mould temperature, injection moulding Moulding shrinkage, free, longitudinal	ISO 1133 ISO 1133 ISO 1133 ISO 1133 ISO 1133 ISO 1133 - - - -	cm³/10min °C kg cm³/10min °C kg °C °C °C %	2 220 10 17 220 21.6 230 - 260 50 - 80 0.4 - 0.7
Mechanical properties			
Tensile modulus Yield stress, 50 mm/min Yield strain, 50 mm/min Nominal strain at break, 50 mm/min Charpy unnotched impact strength (23°C) Charpy unnotched impact strength (-30°C) Charpy notched impact strength (-30°C) Izod notched impact strength (23°C) Ball indentation hardness Force Duration	ISO 527-1/-2 ISO 527-1/-2 ISO 527-1/-2 ISO 527-1/-2 ISO 179/1eU ISO 179/1eU ISO 179/1eA ISO 179/1eA ASTM D 256 ISO 2039-1 ISO 2039-1 ISO 2039-1	MPa MPa % kJ/m ² kJ/m ² kJ/m ² J/m MPa N s	2000 48 4 12 120 80 5 2 100 70 358 30
Thermal properties			
HDT A (1.80 MPa), measured using dried specimens HDT B (0.45 MPa), measured using dried specimens Vicat-Softening-Termperature VST/A/50 Vicat-Softening-Temperature VST/B/50 Max. service temperature (short cycle operation) Coefficient of linear thermal expansion, longitudinal (23-80)°C Thermal conductivity	ISO 75-1/-2 ISO 75-1/-2 ISO 306 ISO 306 - ISO 11359-1/-2 DIN 52612-1	°C °C °C °C E-4/°C W/(m K)	90 94 105 93 75 0.8 - 1.1 0.17
Electrical properties			
Relative permittivity (100Hz) Relative permittivity (1 MHz) Dissipation factor (100 Hz) Dissipation factor (1 MHz) Volume resistivity Surface resistivity Electric strength K20/P50, d = 1 mm	IEC 60250 IEC 60250 IEC 60250 IEC 60250 IEC 60093 IEC 60093 IEC 60243-1	- E-4 E-4 Ohm*m Ohm kV/mm	2.9 2.8 160 140 1E13 1E15 34

Footnotes 1) If the product definition doesn't state otherwise. 2) Specimens according to CAMPUS. 3) The asterisk symbol "" signifies inapplicable properties.