

Product description

Terluran® HD-15 is an easily processable ABS grade with well-balanced mechanical properties and an excellent chemical and stress cracking resistance.

Terluran® HD-15 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 TERLURAN® HD-15 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 Terluran HD-15. The assigned DMF Number is 18858.

Physical form and storage

Terluran® is delivered as spherical pellets. The bulk density of the pellets is from 0.55 to 0.65 g/cm³.

Standard Packaging unit: 25 kg PE-bag on palette, shrunk or wrapped with PE film or delivery in silo trucks.

PE bags should not be stored outside.

In dry areas with normal temperature control, Terluran® pellets can be stored for relatively long periods of time without any change in mechanical properties. Under poor storage conditions, Terluran® absorbs moisture, but this can be removed by drying.

Product safety

No adverse effects on the health of processing personnel have been observed if the products are correctly processed and the production areas are suitably ventilated.

For styrene, acrylonitrile, and 1,3-butadiene the maximum allowable workplace concentrations must be observed according to the pertaining national regulations. In Germany, the following limit values are valid (Oct. 2002): styrene, MAK-value: 20 ml/m³ = 86 mg/m³; acrylonitrile, TRK-value: 3 ml/m³ = 7 mg/m³ and 1,3-butadiene, TRK-value: 5 ml/m³ = 11 mg/m³.

According to EU directive 67/548/EWG, Annex I and TRGS 905 (Oct. 2002), acrylonitrile and 1,3-butadiene are classified as carcinogenic, category 2 ('substances which should be regarded as if they are carcinogenic to man') and 1 (substances known to be carcinogenic to man), respectively.

Experience has shown that during appropriate processing of Terluran 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 Terluran HD safety data sheets.

These can be requested from the Styrenics Infopoint, phone +49 621 60-41446.

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 introduced 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, photographs, 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.

Typical values for uncoloured product at 23 °C ¹⁾	Test method ²⁾	Unit	Values ³⁾
Properties			
Polymer abbreviation	-	-	ABS
Density	ISO 1183	kg/m ³	1050
Water absorption, equilibrium in water at 23°C	similar to ISO 62	%	1
Moisture absorption, equilibrium 23°C/50% r.h.	similar to ISO 62	%	0.22
Processing			
Processing: Injection moulding (M), Extrusion (E), Blow moulding (B)	-	-	M
Melt volume-flow rate MVR 220 °C/10 kg	ISO 1133	cm ³ /10min	15
Pre-drying: Temperature	-	°C	80
Pre-drying: Time	-	h	2 - 4
Melt temperature, injection moulding	-	°C	220 - 260
Mould temperature, injection moulding	-	°C	30 - 60
Moulding shrinkage, free, longitudinal	-	%	0.4 - 0.7
Mechanical Properties			
Tensile modulus	ISO 527-1/-2	MPa	2300
Yield stress, 50 mm/min	ISO 527-1/-2	MPa	38
Nominal strain at break, 50 mm/min	ISO 527-1/-2	%	10
Charpy impact strength (23°C)	ISO 179/1eU	kJ/m ²	170
Charpy impact strength (-30°C)	ISO 179/1eU	kJ/m ²	90
Izod notched impact strength (23°C)	ISO 180/A	kJ/m ²	16
Izod notched impact strength (-30°C)	ISO 180/A	kJ/m ²	6
Charpy notched impact strength (23°C)	ISO 179/1eA	kJ/m ²	14
Charpy notched impact strength (-30°C)	ISO 179/1eA	kJ/m ²	6
Ball indentation hardness at 358 N/30 s	ISO 2039-1	MPa	102
Thermal properties			
HDT A (1.80 MPa)	ISO 75-1/-2	°C	93
HDT B (0.45 MPa)	ISO 75-1/-2	°C	99
Vicat softening temperature VST/B/50	ISO 306	°C	100
Max. service temperature (short cycle operation)	-	°C	80
Coefficient of linear thermal expansion, longitudinal (23-80)°C	ISO 11359-1/-2	E-4/°C	0.8 - 1.1
Thermal conductivity	DIN 52612-1	W/(m K)	0.17
Electrical properties			
Relative permittivity (100Hz)	IEC 60250	-	2.9
Relative permittivity (1 MHz)	IEC 60250	-	2.8
Dissipation factor (100 Hz)	IEC 60250	E-4	48
Dissipation factor (1 MHz)	IEC 60250	E-4	79
Volume resistivity	IEC 60093	Ohm*m	1E13
Surface resistivity	IEC 60093	Ohm	1E13
Electric strength K20/P50, d = 0.6 - 0.8 mm	IEC 60243-1	kV/mm	37
Comparative tracking index, CTI, test liquid A	IEC 60112	-	600
Comparative tracking index, CTIM, Test liquid B	IEC 60112	-	225

Footnotes

1) If product name or properties don't state otherwise.

2) Specimens according to CAMPUS.

3) The asterisk symbol "*" signifies inapplicable properties.