

**Material Code M0480**

**Revision 01**

**Type** ABS  
**Brand name** TERLUX 2802 HD  
**Supplier** STYROLUTION/BASF

**Sterilization Stability:**

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	Up to 50 kGy
Ethylene Oxide	YES	-

**Biocompatibility Data:**

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-

**Main Regulatory Compliances:**

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Food Contact	YES	Regulation (EU) No.10/2011
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Pharmacopoeia	YES	EUP, 7th Edition, Chap. 3.2.2. "Plastic Containers and Closures"
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
US Pharmacopoeia	YES	USP Class Biological Reactivity Tests Class VI
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

**Technical Characteristics:**

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	1080 kg/m <sup>3</sup>	ISO 1183	-
Color	Transparent	-	-
Melt Flow Rate	17 cm <sup>3</sup> /10 min	ISO 1133	at 220 °C/ 2.16 kg
Modulus of Elasticity / Young modulus	2000 MPa	ISO 527	-
Tensile Strength at Yield	48 MPa	ISO 527	-
Hardness	70 MPa	ISO 2039-1	(Ball Indentation)
Impact strength	4 %	ISO 527	Tensile Strain at Yield

<b>R&amp;D Validation Date</b>	ABO 1-Sep-2018	<b>QA/RA Validation Date</b>	CGI 3-Aug-2018
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Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promepla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promepla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.