

Material Code M0933

Revision 00

Type PC
Brand name Lexan HP2REU
Supplier SABIC

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	up to 25kGy
Ethylene Oxide	YES	-
Autoclave	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Implantation	YES	ISO 10993-6	-
Hæmocompatibility	YES	ISO 10993-4	-

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	NO	< 100ppm
Food Contact	YES	-
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	No BSE risk
US Pharmacopoeia	YES	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	1.2 g/cm3	ISO 1183	-
Color	Various - Natural	-	-
Melt Flow Rate	22 g/10 min	ASTM D 1238	300°C/1.2 kgf
Modulus of Elasticity / Young modulus	2350 MPa	ISO 527	1 mm/min
Tensile Strength at Break	65 MPa	ISO 527	50 mm/min
Tensile Strength at Yield	63 MPa	ISO 527	50 mm/min
Other mechanical property 1	6%	ISO 527	tensile strain, yield 50 mm/min
Other mechanical property 2	90 MPa	ISO 527	fluxural stress, yield 2mm/min

R&D Validation	FRA	QA/RA Validation	CGI
Date	25-08-2017	Date	13-09-2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promeppla 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 Promeppla 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.