

Material Code M0053
Revision 00

Type PA
Brand name Zytel 101F Nylon Resin
Supplier DuPont

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	-
Ethylene Oxide	YES	-
Autoclave	YES	-

Biocompatibility Data:

<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
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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
Conflict Minerals	YES	Not used in the manufacturing process
Food Contact	YES	FDA 21CFR 177.1500
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
Polyvinyl Chloride (PVC)	YES	Not used in the manufacturing process
TSE / BSE	YES	Contains minor quantity of a component derived from bovine tallow sources. Subjected to rigorous processes of hydrolysis
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	1140/- kg/m ³	ISO 1183	-
Viscosity	140/* cm ³ /g	ISO 307, 1157, 1628	-
Modulus of Elasticity / Young modulus	1400 MPa	ISO 527-1/ -2	-
Tensile Elongation at Break	> 50%	ISO 527-1/ -2	-
Tensile Strength at Yield	55 MPa	ISO 527-1/ -2	-

R&D Validation	FRA	QA/RA Validation	CGI
Date	23-11-2017	Date	23-11-2017

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.