

Material Code M1259

Revision 00

Type PP
Brand name RP340R
Supplier BRASKEM/ MAXIO

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Ethylene Oxyde	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
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	-

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	FDA 21CFR177.1520/ Regulation EC 1935/2004
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	Directive 94/62/EC
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	Not used in the manufacturing process
US Pharmacopoeia	YES	USP 33
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-
Vide 5	TOY	European standard EN71-3

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	0.902 g/ cm3	ISO 1183-1	-
Melt Flow Rate	25 g/ 10min	ISO 1133	-
Tensile Strength at Yield	31 MPa	ISO 527-1	-

Document status : VALID

R&D Validation	ABO	QA/RA Validation	CGI
Date	6-Dec-2018	Date	14-06-2018

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.