

Material Code M0028

Revision 00

Type PP
Brand name PURELL HP371P
Supplier LYONDELLBASELL

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	-
Ethylene Oxyde	YES	-
Autoclave	YES	-
E-Beam	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	Chapter 88
Sensitization	YES	-	-
Irritation or intracutaneous reactivity	YES	-	-
Systemic toxicity (acute)	YES	-	-
Implantation	YES	-	-

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
Drug Master File	YES	Information is listed in DMF N. 13038. Contact LyondellBasell for a DMF authorization letter to be sent to FDA.
Food Contact	YES	Regulation 1935/2004/EC - Regulation 2023/2006/EC (GMP) - Regulation 10/2011/EC.
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	-
European Directive 2002/16/EC - Epoxy Derivatives	YES	Not used in the manufacturing process
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Pharmacopoeia	NO	Presence of additives not listed in the relevant EP monographs
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	-
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	0.9 g/cm3	ISO 1183	At 23°C
Melt Flow Rate	18g/10min	ISO 1133	MFR 230°C/2.16Kg
Modulus of Elasticity / Young modulus	1250 MPa	ISO 527	-
Tensile Strength at Break	>50%	ISO 527-1/-2	-
Tensile Strength at Yield	31 MPa	ISO 527-1/-2	-
Impact strength	170 kJ/m ²	ISO 179	Charpy unnotched impact strength (23 °C)

R&D Validation	GVA	QA/RA Validation	ABA
Date	10/05/17	Date	10/05/17

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.