

**Material Code M0075**

**Revision 00**

**Type** LDPE  
**Brand name** RIBLENE FH 20  
**Supplier** ENICHEM

**Sterilization Stability:**

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

**Biocompatibility Data:**

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-
Cytotoxicity	YES	-	-
Hæmocompatibility	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
Food Contact	YES	-
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Pharmacopoeia	YES	III Ed.
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
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>
Extrusion	YES	-	Blown film extrusion
Injection	YES	-	-
Density	0.923 g/cm3	ISO 1133	-
Melt Flow Rate	1.1 g/10min	ISO 1183	190 °C/ 2.16 kg
Tensile Strength at Break	25 MPa	ISO 527-3	MD
Hardness	46±2 ShA	ASTM D 2240	15 Secondes
Other mechanical property 1	350%	ASTM D 882 B	Elongation at break MD

<b>R&amp;D Validation</b>	GVA	<b>QA/RA Validation</b>	CGI
<b>Date</b>	12/05/17	<b>Date</b>	12/05/17

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.