

Material Code M0024

Revision 00

Type PVC
Brand name hy-vin®VQ130
Supplier Ineos Compounds

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	32 KGy, yellow 1/16
Ethylene Oxyde	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	showed no cytotoxic potential
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	met the requirements of the intracutaneous injection test
Hæmocompatibility	YES	ISO 10993-4	shows no hæmolytic potential

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	Formulation
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
TSE / BSE	YES	Not used in the manufacturing process
US Pharmacopoeia	YES	Class VI biological tests for plastics
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	-	The following conditions have proved
Density	1347 kg/m ³	B.S. 2782	-
Color	clear	-	-
Hardness	78 ShD	B.S. 2782	-

R&D Validation		QA/RA Validation	
Date		Date	

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.