

Material Code M0365
Revision 00

Type HDPE
Brand name Purell GC 7260
Supplier LyondellBasell/ Albis Plastics

Sterilization Stability:

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

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	and met the USP limits defined in Chapter 661.
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
Conflict Minerals	YES	Not used in the manufacturing process
Drug Master File	YES	Information on this product is listed in DMF N. 5654
Food Contact	YES	Regulation 1935/2004/EC, 2023/2006/EC (GMP), 10/2011/EC (PIM)
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	complies with the directive 94/62/EC
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Pharmacopoeia	YES	3.1.3 /Edition 9.0
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3".
US Pharmacopoeia	YES	<88>/ <661>
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	0.960 g/cm3	ISO 1183	-
Melt Flow Rate	8 g/ 10min	ISO 1133-1	190°C/ 2.16kg
Modulus of Elasticity / Young modulus	1350 MPa	ISO 527-1, -2	-
Hardness	64 ShD	ISO 868	Shore D
Impact strength	4 kJ/m²	ISO 179	-

R&D Validation	GVA	QA/RA Validation	CGI
Date	08/07/2017	Date	23-08-2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promepila 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 Promepila 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.