Teldene® H12ML-MG

Polypropylene Homopolymer for Healthcare Applications

NATPET

Technical Data Sheet

Product description

NATPET polypropylene grades for healthcare applications are produced under controlled conditions to ensure consistent quality and contamination free resins.

H12ML-MG is a Homopolymer for injection molding application. Produced using Spheripol® technology, the grade has an exceptional advantage of having morphologically uniform resins, medium flow ability and high stiffness.

It is recommended that all potential activities for applications of this grade in the healthcare area have to be discussed with the relevant technical and business representative of *NATPET particularly* for use of this product in an implantable device that is introduced into the human body by surgical intervention and is intended to remain in place following surgical procedure.

Processing Method

- Injection Molding

Properties	*Conditions*	*Method*	*Value*	*Unit*
Density	23°C	ISO 1183	*0.900*	g/cm^3
Melt Flow Rate (MFR)	230°C/2.16 kg	ASTM D 1238-13	*12*	g/10-min
Mechanical				
Flexural Modulus		ISO 178	*1,500*	MPa
Tensile Modulus	1-mm/min	ISO 527	1,550	MPa
Tensile Stress at Break	50-mm/min	ISO 527	*26*	MPa
Tensile Stress at Yield	50-mm/min	ISO 527	*35*	MPa
Tensile Strain at Break	50-mm/min	ISO 527	*> 50*	%
Tensile Strain at Yield	50-mm/min	ISO 527	*13*	%
Izod $_{Notched}$	23°C	ISO 180	*3.9*	kJ/m^2
Thermal				
Heat Deflection Temperature	0.45 MPa Un-annealed	ISO 75B	*91*	°C
Vicat Softening Temperature	A50 (50°C/h 10N)	ISO 306	*152*	°C

Technical information

Note: The above are typical data representing the product; not to be construed as analysis certificate or specifications.

For further details about ***NATPET*** and its products, please visit the website at www.natpet.com

NATPET® products, marketed under the trade name Teldene®, are intended for the use by those customers and/or any other consumers, who undertake to become responsible to independently establish on their own the appropriateness of the product for its intended use, covering all safety and legally enacted requirements at the location of its projected use and the legal disposal practices thereof. The description of the product as given in this sheet shall under no circumstances be construed as warranty, express or implied including a warranty of merchandize fitness for a particular purpose. On behalf of NATPET, no one is authorized to make any such warranties, or take up on their own to assume such a liability. In case of product related claims, the sole and maximum remedy will be the physical substitution of the product or reimbursement of the purchase value, as per NATPET's options. Further claims based on consequential, secondary, castigatory, or extraordinary damages will in no way entertained by NATPET.
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Special Features

- Shows broad processing window while providing good mechanical properties
- Tested for biocompatibility, ISO 10993 (Biological Evaluation of Medical Devices). Refer to "**RCPD**"

Processing Conditions

- Average extruder temperature range may be kept between 240 - 260°C.
- Under high humidity condition it is recommended to dry resin before use to evaporate any moisture content during processing.

Food Regulation

This product is defined as a preparation under specific food contact regulation. Detailed information will be provided in a relevant document "Regulatory Compliances Product Declaration (**RCPD**)" upon request.

Storage and Handling

If the resin is stored under adverse conditions, i.e. if there are large fluctuations in ambient temperature and the atmospheric humidity is high, moisture may condense inside the packaging. Under these circumstances, it is recommended to dry the resin before use. Unfavorable storage conditions may also intensify the resin´s slight characteristic odor.

Polypropylene resin should be stored to prevent a direct exposure to sunlight (UV) and heat. Improper storage can initiate degradation. Therefore the resin must be protected from direct sunlight, temperatures above 40°C and high atmospheric humidity during storage. The resin can be stored over a period of more than 6 month without significant changes in the specified properties, appropriate storage conditions provided. Higher storage temperatures reduce the storage time. Please refer to Safety Data Sheet (**SDS**) for handling and storage information.

Documents

Legal documents and Safety Data Sheets (**SDS**) are available on request. Please send your request to the following e-mail: pa@natpet.com

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Disclaimer

Before using this product users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally. NATPET makes no warranty; express or implied (including any warranty of merchantability or fitness for a particular purpose or any warranty) other than as separately agreed to by the parties in a contract.

This product(s) may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application: (i) U.S. FDA Class I or II Medical Devices; Health Canada Class I, II or III Medical Devices; European Union Class I or II Medical Devices; (ii) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices; (iii) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (iv) tobacco related products and applications, electronic cigarettes and similar devices.

The product(s) may not be used in: (i) U.S. FDA Class III Medical Devices; Health Canada Class IV Medical Devices; European Class III Medical Devices; (ii) applications involving permanent implantation into the body; (iii) life-sustaining medical applications.

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