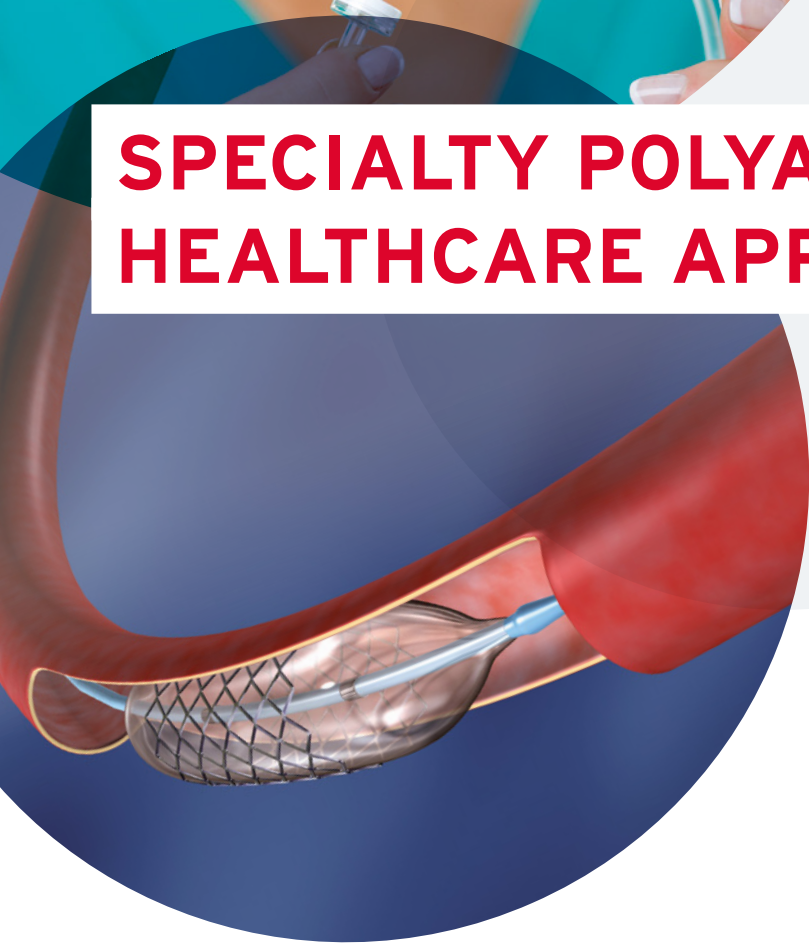




VELOX
Specialities in Motion

SPECIALTY POLYAMIDES FOR HEALTHCARE APPLICATIONS



ARKEMA
INNOVATIVE CHEMISTRY

PEBAX[®]
MED
BY ARKEMA

RILSAMID[®]
MED
BY ARKEMA

RILSAN[®]
MED
BY ARKEMA

RILSAN[®]
CLEAR MED
BY ARKEMA

PEBAX® MEDICAL GRADE POLYMERS

Medical grades Pebax® polyether block amide are plasticiser-free thermoplastic elastomers with a wide range of physical and mechanical properties achieved by varying the monomeric block types and ratios. Grades within the product range extend from soft and flexible products similar to elastomers, to those with mechanical properties approaching polyamides.

The remarkable processing ease of medical grade Pebax® elastomers makes it an excellent choice for extrusion of medical grade tubing or film applications and injection moulding. Other unique properties include:

- Pebax® MED grades have undergone testing in accordance with certain portions of the USP Class VI and/or ISO 10993 standards.
- Sterilisation feasibility

- Bondable by adhesives or RF welding
- Easily blended with other polymers and compounded with additives
- High torque transference and kink resistance
- Excellent impact resistance and low rigidification at low temperature
- Consistent durometer and flexibility at room and body temperatures
- Good resistance to most chemicals
- Pebax® MV 1074 SA 01 MED: hydrophilic grade with antistatic properties (surface resistivity $3.10^9 \Omega / \text{sq.}$)

| | | | | MEDICAL GRADE RANGE | | | | | | | | | |
|-----------------------|---|-----------------|-------------------|---------------------|----------------|----------------|----------------|--------------------------|----------------|----------------|----------------|----------------|----------------|
| | | | | PEBAX® | | | | | | | | | |
| PROPERTIES | DESCRIPTION | TEST METHOD | UNITS | MV 1074 SA 01 MED | 2533 SA 01 MED | 3533 SA 01 MED | 4033 SA 01 MED | 4533 SA 01 MED (MX 1205) | 5533 SA 01 MED | 6333 SA 01 MED | 7033 SA 01 MED | 7233 SA 01 MED | 7433 SA 01 MED |
| DENSITY | | ISO 1183 | g/cm ³ | 1.07 | 1.00 | 1.00 | 1.00 | 1.01 | 1.01 | 1.01 | 1.01 | 1.01 | 1.01 |
| WATER ABSORPTION | @20°C, 50% RH | ISO 62 | % | 1.4 | 0.4 | 0.4 | 0.5 | 0.4 | 0.6 | 0.7 | 0.7 | 0.7 | - |
| | @23°C, 24 hrs in water | ISO 62 | % | 48 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.1 | 1.1 | 0.9 | - |
| MELTING POINT | | ISO 11357 | °C | 158 | 134 | 144 | 160 | 147 | 159 | 169 | 172 | 174 | 174 |
| VICAT POINT | Under 1 daN | ISO 306 | °C | - | 58 | 77 | 131 | 111 | 142 | 157 | 164 | 164 | - |
| SHRINKAGE | Flow direction, after 24 hrs, 4 mm, mould at 20°C | Internal Method | % | - | 0.5 | 0.5 | 0.4 | 0.4 | 1.2 | 1.2 | 1.2 | 1.2 | 0.2*** |
| | Transverse direction, after 24 hrs, 4 mm, mould at 20°C | Internal Method | % | - | 0.8 | 0.8 | 1.1 | 1.1 | 1.4 | 1.4 | 1.5 | 1.5 | 0.7*** |
| HARDNESS SHORE* | Instantaneous | ISO 868 | Shore D | 40 | 27 | 33 | 42 | 46 | 54 | 64 | 69 | 69 | 73 |
| | After 15 sec | ISO 868 | Shore D | - | 22 | 25 | 35 | 41 | 50 | 58 | 61 | 61 | 66 |
| TENSILE TEST* | Stress at Break | ISO 527 | MPa | 30 | 32 | 39 | 40 | 42 | 52 | 53 | 54 | 56 | 46 |
| | Strain at Break | ISO 527 | % | >700 | >750 | >600 | >450 | >550 | >450 | >350 | >350 | >300 | >250 |
| FLEXURAL MODULUS* | | ISO 178 | MPa | 80 | 12 | 21 | 77 | 86 | 170 | 285 | 390 | 510 | 610 |
| CHARPY IMPACT | Unnotched 23°C | ISO 179 | kJ/m ² | - | NB | NB | NB | NB | NB | NB | NB | NB | NB |
| | Unnotched -30°C | ISO 179 | kJ/m ² | - | NB | NB | NB | NB | NB | NB | NB | NB | NB |
| | V-notched 23°C | ISO 179 | kJ/m ² | - | NB | NB | NB | NB | NB | NB | 120 (p) | 15 (c) | 19 (c) |
| | V-notched -30°C | ISO 179 | kJ/m ² | - | NB | NB | NB | NB | NB | 20 (c) | 20 (c) | 10 (c) | 6 (c) |
| PROCESSING | | | | MV 1074 SA 01 MED | 2533 SA 01 MED | 3533 SA 01 MED | 4033 SA 01 MED | 4533 SA 01 MED (MX 1205) | 5533 SA 01 MED | 6333 SA 01 MED | 7033 SA 01 MED | 7233 SA 01 MED | 7433 SA 01 MED |
| DRYING** | Time | | hrs | 4-6 | 4-8 | 4-8 | 4-8 | 4-8 | 4-6 | 4-6 | 5-7 | 5-7 | 5-7 |
| | Temperature | | °C | 65-75 | 55-65 | 55-65 | 60-70 | 60-70 | 65-75 | 65-75 | 70-80 | 70-80 | 70-80 |
| EXTRUSION TEMPERATURE | Minimum | | °C | 210 | 190 | 190 | 210 | 210 | 210 | 210 | 220 | 220 | 220 |
| | Recommended | | °C | 220 | 205 | 205 | 220 | 220 | 220 | 225 | 235 | 235 | 235 |
| | Maximum | | °C | 230 | 220 | 220 | 230 | 230 | 230 | 240 | 250 | 250 | 250 |
| INJECTION TEMPERATURE | Minimum | | °C | 200 | 180 | 180 | 200 | 200 | 200 | 230 | 230 | 230 | 230 |
| | Recommended | | °C | 240 | 210 | 210 | 240 | 240 | 240 | 260 | 260 | 260 | 260 |
| | Maximum | | °C | 270 | 240 | 240 | 270 | 270 | 270 | 290 | 290 | 290 | 290 |
| MOULD TEMPERATURE | Typical | | °C | 25-60 | 10-30 | 10-30 | 10-30 | 10-30 | 25-60 | 25-60 | 25-60 | 25-60 | 25-60 |

+ Samples conditioned 15 days at 23°C, 50% RH
 ++ Pebax® is delivered dried in sealed packaging ready to be processed. Drying is only necessary for bags opened for more than 2 hours
 +++ mould at 40°C (c) Complete break (p) Partial break

RILSAN® AND RILSAMID® MEDICAL GRADE POLYAMIDES

Medical grades Rilsan® polyamide 11 and Rilsamid® polyamide 12 are thermoplastic polymers used in applications that require the strength and performance characteristics of a true thermoplastic, yet still offer sufficient flexibility and elongation approaching that of some elastomers. Rilsan® and Rilsamid® polymers are easy to process by most methods, including extrusion, extrusion blow moulding, injection moulding and rotomoulding. Exceptional properties of these polyamide products include:

- High strength and mechanical resistance
- Excellent resistance to chemicals (particularly hydrocarbons)
- Ease of processing

- Wide range of working temperatures [-40°C -130°C (40°F -266°F)]
- High dimensional stability and low density
- Very low gas permeation

RILSAN® CLEAR MED

Medical grades Rilsan® Clear offer the best combination of transparency, light weight and flexibility of transparent polymers commonly used in medical applications.

| | | | | MEDICAL GRADE RANGE | | | | | | | |
|-----------------------------------|--|-----------------|-------------------|---------------------|-----------------|-----------------|---------------|-----------------|-----------------|-----------------|--|
| | | | | RILSAN® | | | RILSAN® CLEAR | | RILSAMID® | | |
| PROPERTIES | DESCRIPTION | TEST METHOD | UNITS | BMNO MED | BESNO MED | BESVOA MED | G 170 MED | G 850 Rnew® MED | AMNO MED | AESNO MED | |
| NATURE & DESIGNATION | | ISO 1874 | - | PA11, M, 12-010 | PA11, E, 22-010 | PA11, E, 22-010 | | | PA12, M, 12-010 | PA12, E, 22-010 | |
| BIO BASED CARBON | calculation | ASTM 6866 | % | 100 | 100 | 100 | - | 49-51 | - | - | |
| DENSITY | | ISO 1183 | g/cm ³ | 1.03 | 1.02 | 1.02 | 1.05 | 1.01 | 1.01 | 1.01 | |
| WATER ABSORPTION | @20°C, 50% RH | ISO 62 | % | 0.75 | 0.75 | 0.75 | 1.3 | 1.7 | 0.7 | 0.7 | |
| | @23°C, 24 hrs in water | ISO 62 | % | 0.95 | 0.95 | 0.95 | 3.2 | 4 | 0.9 | 0.9 | |
| MELTING POINT | | ISO 11357 | °C | 189 | 186 | 186 | - | - | 180 | 180 | |
| GLASS TRANSITION TEMPERATURE | Tg | ISO 11357 | - | - | - | - | 168 | 150 | - | - | |
| HEAT DEFLECTION TEMPERATURE (HDT) | under 0.45 Mpa | ISO 75 | °C | 145 | 145 | 145 | 150 | 135 | 130 | 130 | |
| | under 1.80 Mpa | ISO 75 | °C | 50 | 50 | 50 | 136 | 120 | 50 | 50 | |
| TRANSPARENCY | 560 nm, 2 mm | ASTMD 1003-97 | - | - | - | - | 90,8 | 91,7 | - | - | |
| SHRINKAGE | flow direction, after 24 hrs, 2 mm, mould @ 30°C | Internal Method | % | 0.9 | n/a** | n/a** | 0.69 | 0.6 | 0.8 | n/a** | |
| | transverse direction, after 24 hrs, 2 mm, mould @ 30°C | Internal Method | % | 0.9 | | | 0.72 | 0.75 | 0.8 | | |
| HARDNESS SHORE* | Instantaneous | ISO 868 | Shore D | 75 | 76 | 76 | 84 | 80 | 74 | 74 | |
| | After 15 sec | ISO 868 | Shore D | 68 | 71 | 71 | 79 | 78 | 69 | 70 | |
| TENSILE TEST* | Stress at Yield | ISO 527 | MPa | 41 | 40 | 36 | 74 | 51 | 37 | 38 | |
| | Strain at Yield | ISO 527 | % | 5 | 6 | 5 | 9 | 7.6 | 8 | 5 | |
| | Stress at Break | ISO 527 | MPa | 58 | 50 | 52 | 58 | 58 | 62 | 47 | |
| | Strain at Break | ISO 527 | % | >200 | >200 | >200 | >100 | >140 | >200 | >200 | |
| TENSILE MODULUS* | | ISO 527 | MPa | 1280 | 1200 | 1180 | 2020 | 1622 | 1100 | 1260 | |
| FLEXURAL MODULUS* | | ISO 178 | MPa | 1140 | 1130 | 1100 | 1980 | 1600 | 920 | 1060 | |
| CHARPY IMPACT | Unnotched 23°C | ISO 179 | kJ/m ² | NB | NB | NB | NB | NB | NB | NB | |
| | Unnotched -30°C | ISO 179 | kJ/m ² | NB | NB | NB | NB | NB | NB | NB | |
| | V-notched 23°C | ISO 179 | kJ/m ² | 20 | 15 | 15 | 13 | 11 | 5 | 11 | |
| | V-notched -30°C | ISO 179 | kJ/m ² | 10 | 13 | 13 | 13 | 9 | 6 | 8 | |
| PROCESSING CONDITIONS | | | | BMNO MED | BESNO MED | BESVOA MED | G 170 MED | G 850 Rnew® MED | AMNO MED | AESNO MED | |
| DRYING** | Time | | hrs | 4-6 | 4-6 | 4-6 | 4-6 | 4-6 | 4-6 | 4-6 | |
| | Temperature | | °C | 80-90 | 65-80 | 65-80 | 90 | 90 | 80-90 | 65-80 | |
| EXTRUSION TEMPERATURE | Minimum | | °C | | 230 | 230 | 270 | - | | 230 | |
| | Recommended | | °C | n/a* | 250 | 250 | 280 | - | n/a* | 240 | |
| | Maximum | | °C | | 280 | 280 | 290 | - | | 270 | |
| INJECTION TEMPERATURE | Minimum | | °C | 240 | | | 270 | 250 | 230 | | |
| | Recommended | | °C | 270 | n/a** | n/a** | 290 | 280 | 250 | n/a** | |
| | Maximum | | °C | 290 | | | 310 | 300 | 280 | | |
| MOULD TEMPERATURE | Typical | | °C | 25-60 | n/a* | n/a* | 40-80 | 20-80 | 20-40 | n/a* | |

+ Samples conditioned 15 days at 23°C, 50% RH
 ++ Rilsan® Clear, Rilsan® and Rilsamid® are delivered dried in sealed packaging ready to be processed. Drying is only necessary for bags opened for more than 2 hours
 * Injection grade ** Extrusion grade





EUROPE

AUSTRIA

BENELUX

CZECH REPUBLIC

DENMARK

FINLAND

FRANCE

GERMANY

ITALY

NORWAY

POLAND

PORTUGAL

ROMANIA

RUSSIA

SPAIN

SWEDEN

TURKEY

UK

ASIA

CHINA

RILSAN®, PEBAX®, RILSAMID® AND RNEW® ARE REGISTERED TRADEMARKS OF ARKEMA FRANCE.

Arkema has implemented an internal Medical Device Policy regarding the use of Arkema products in medical device applications that are in contact with the body or circulating bodily fluids. Arkema has designated specific medical grades to be used for such Medical Device applications. Products that have not been designated as medical grades are not authorised by Arkema for use in medical device applications that are in contact with the body or circulating bodily fluids.

In addition Arkema strictly prohibits the use of any polymers, including medical grades, in applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. Unless Arkema otherwise expressly agrees by written contract, the Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices. Further, all implantable medical devices, whether permanent or temporary, carry a risk of adverse consequences. With regard to implantable medical devices, you should not rely upon the judgment of Arkema. Any decision regarding the appropriateness of a particular medical device in a particular medical application or for a specific clinical use should be based upon the judgment of your physician, medical device supplier and the United States Food & Drug Administration and/or the European process of Medical Device notification. Unless otherwise specifically stated by Arkema in writing, Arkema does not perform clinical medical studies on implantable medical devices. Arkema cannot weigh the benefits against the risks of a device and does not offer a medical judgment on the safety or efficacy of use of any Arkema product in a medical device.

The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability, express or implied with respect to:

- the information provided;
- the Products including, without limitation, merchantability, fitness for a particular purpose or the results to be derived from the use of the Products
- the suitability of any product for use in any specific medical device, or other product, or for any medical application.

The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialisation. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See Safety Data Sheet for Health & Safety Considerations.

A designer of materials and innovative solutions, Arkema shapes materials and creates new uses that accelerate customer performance. Our balanced business portfolio spans high-performance materials, industrial specialties and coating solutions. Our globally recognised brands are ranked among the leaders in the markets we serve. Reporting annual sales of €7.7 billion in 2015, we employ approximately 19,000 people worldwide and operate in close to 50 countries. We are committed to active engagement with all our stakeholders. Our research centers in North America, France and Asia concentrate on advances in bio-based products, new energies, water management, electronic solutions, light-weight materials and design, home efficiency and insulation.

VELOX GmbH

Anne Bartels

Brandstwierte 1, 20457 Hamburg

Tel: +49 (0)40 369 688 0 • Fax: +49 (0)40 369 688 88

Email: medical@velox.com • www.velox.com

**FIND OUT MORE ABOUT
OUR SERVICES**

