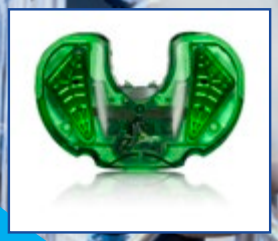
covestro



# Medical Reference Guide

High Performance Materials
for the Healthcare Industry

# Patients depend on doctors.

Doctors and other healthcare professionals depend on medical devices to save or improve lives.

Those who design medical devices depend on **Covestro,** one of the leading producers of high-performance plastics around the world.


Polycarbonates from Covestro are responsible for some of modern medical technology's essential devices and the development of next generation life-saving technology. In products ranging from insulin pens and pumps, inhalers, renal care and blood management to heart defibrillators, intravenous access components and surgical instruments used to assist patients — polycarbonate is there and so is Covestro.

For more than 150 years Covestro has practiced Cutting-Edge Chemistry. Polycarbonates from Covestro exemplify the safety and innovation that medical device manufacturers across the world have come to know and trust.

**The needs are real, and the ideas to meet those needs are here ...**

**Covestro helps them materialize.**

# Covestro High-Performance Materials For Medical Applications

## A Reference Guide

This brochure reviews our polycarbonate-based materials for use in medical applications. Included are typical applications, their performance requirements and the Covestro materials that may meet those requirements. Our intent is to provide a general overview of these materials and their performance characteristics specific to the healthcare industry.

## Table of Contents



Apec® Bayblend® Makroblend® Makrolon®

# Typical Medical Applications

Covestro offers high-performance materials that are used in demanding applications in the healthcare industry. Medical device manufacturers have come to rely on Covestro to provide technically advanced materials that can help meet the critical design, manufacturing and end-use performance parameters of a variety of medical device and healthcare applications.

## Blood Management

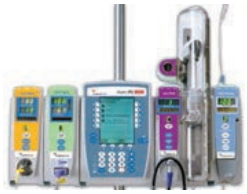
This whole blood processing system gives clinicians increased flexibility in how they process blood. Makrolon® 2558 polycarbonate met the glass-like clarity, impact resistance, biocompatibility and high tensile and flexural strength requirements of its manifold, centrifuge plate and centrifuge lid.

This blood collection system required a sufficient heat resistance to withstand super-heated steam sterilization at 121°C. Makrolon® fulfilled this requirement and it permits a visual check of the blood flow. This Makrolon® grade meets the FDA biocompatibility requirements of ISO 10993-1.

Makrolon® 2558 polycarbonate was selected in key components, including the connectors (top) used where the catheters enter the femoral arteries, and the unique blood pump (bottom), which uses magnetic levitation to create a low-friction environment that does not damage blood cells.

The housing of the adsorber system is made from impact-resistant Makrolon® 2458 polycarbonate, which can withstand pressurized hot-steam sterilization where temperatures reach at least 121°C for more than 20 minutes.

## Patient Monitoring and Diagnostics



Bayblend® FR PC+ABS blend utilized in the medication safety system offers toughness, dimensional stability, flame retardance and moldability.

The intrapartum monitor relies on Bayblend® FR 3010 PC+ABS blend to provide monitoring of the fetal heartbeat throughout labor.

## Renal Therapy


Dialysis filters remove impurities from the blood of patients with impaired kidney function. Makrolon® was selected for the canister and end-caps for its glass-like clarity, superior impact resistance, weldability and sterilizability.

# Typical Medical Applications

## Cardiovascular

Blood extracted from the thorax during surgery is collected in a cardiotomy reservoir (shown), treated in a hematocrit and returned to the patient. Makrolon® polycarbonate was selected as a rugged material for the housing. Its high transparency facilitates rapid visual inspection.

Bayblend® FR3010 was chosen for the automated external defibrillator (AED) battery case and housing based on the material's superior impact performance, overall strength and flame retardancy to provide durability without sacrificing life-saving features.

This intranasal cooling system is used for therapeutic hypothermia to help improve survival following cardiac arrest. Bayblend® FR3010 was selected for multiple components to take advantage of its strength, flame retardancy and chemical resistance for increased portability and toughness.

This blood cardioplegia device is used in cardiac surgery to cool and warm blood. It is about as large as a human fist, a breakthrough in size for this type of device. The device's structural strength, biocompatibility and clarity are provided by a medical grade of Makrolon® polycarbonate.

This advanced medical device for heart attack treatment required a material that was clear, easily moldable and met FDA regulations. The material also needed to be from a dependable supplier that could deliver a consistent product on a long-term basis. The application met these requirements with Makrolon® 2558 polycarbonate.

## Home Care

Bayblend® FR PC+ABS blend was chosen for the door, top, base and monitor housing of the medication management device. The durability, performance and special coloring capabilities of the Bayblend® resin made it the ideal material to use for this novel medication management system.

# Typical Medical Applications

## Respiratory

Inflating bellows are required by rescue services, hospitals and practicing doctors whenever immediate respiration is necessary. Transparent Apec® polycarbonate, a high heat material, was selected for the safety valve because it can easily be cleaned and sterilized for repeated use.

The portable oxygen concentrator is designed to help patients who need therapeutic oxygen. The concentrator's shell is constructed of six separate components molded from Bayblend® FR 3010. The external battery housing is also made of three components molded from the same material.

This innovative sinus therapy device used Makrolon® polycarbonate because of its low-viscosity, high-performance properties such as a good balance of flame retardancy, toughness, stiffness and heat resistance. The high-clarity polycarbonate enabled its container to have a translucent blue appearance.

## Drug Delivery

The needle-free injection device (shown), is capable of delivering up to 30 doses from a single medication reservoir. Each dose of medicine will be delivered through a cassette with a nozzle component molded from Makrolon® Rx2530 polycarbonate.

This needleless injection system can be used for many different liquid medication that have to be administered subcutaneously. The chosen Makrolon® grade has the advantage to withstand gamma irradiation sterilization without yellowing and pressures up to 30 MPa during injection.

Modern powder inhalation devices require the use of high performance thermoplastic materials. Makrolon® was chosen as an ideal material for some of the housing parts due to its high dimensional stability, good processability and strong mechanical performance to maximize the reliability for daily use of this device.

The needle guard utilizes Makrolon® Rx1851 because it offers improved flow, lubricity and easy release characteristics. It has enhanced mold release technology that provides increased design flexibility for complicated parts. The anti-needle-stick device is used for prefilled injectable syringe applications.

An auto-injector for patients at risk for anaphylaxis, a severe allergic reaction, utilized Makrolon® 2458 polycarbonate because it is a high-flow resin and highly moldable. The part of the device that touches the patient during injection was molded from Bayblend® M850 XF for its biocompatibility, rigidity, as well as dimensional and color stability.

# Typical Medical Applications

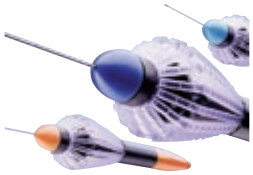
## IV Access

The needleless access connector Y-site with integrated check valve was made with Makrolon® Rx1805 polycarbonate resin. The check valve features increased resistance to chemical attack from intravenous fluid products, such as lipid emulsions, and "true swabability," meaning the valves can be readily disinfected and reactivated.

Makrolon® Rx1805 polycarbonate was chosen to produce a closed, no drip, male luer connector that is used for administering cytotoxic drugs and reducing the risk of medications contacting healthcare workers. This device features a unique visual indicator confirming the connection status. In addition to strength and clarity, Makrolon offers lipid/chemical resistance, biocompatibility and gamma stability.

Makrolon® Rx1805 lipid-resistant polycarbonate resin has been selected for a variety of IV access components including three-way stopcocks and manifolds.

## Surgical

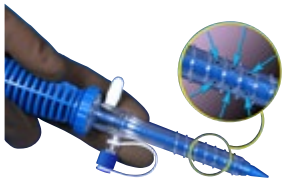


The micro forceps and scissors were developed to combat retinal disease. Makrolon® Rx2530 was selected for the basket component and Makrolon® 2458 polycarbonate for the other seven components. A unique feature of the instrument line is a version with luminous forceps made of Makrolon polycarbonate. The device highlights design and mechanical flexibility that can be obtained with components made from Makrolon®.

This sterilizer, molded from Apec® 1745, offers proven performance and features a unique combination of properties, including high heat-resistance, impact strength and glass-like transparency. These properties are ideal for supporting and enhancing the sterilization process of small, non-invasive medical devices, a growing trend for medical technological advancements.

The surgical bone stapler provides superior and instantaneous bone compression force designed to improve bone healing and reduce complications and healthcare costs. After material property evaluations, Makrolon® Rx2530 polycarbonate was selected because of its high strength, temperature stability, clarity and biocompatibility.

This knee balancer provides precise, quantitative intraoperative data on soft tissue balancing during total knee replacement surgery. Criteria for choosing a material for this innovative product included biocompatibility, superior strength, improved flow, lubricity and availability of custom color formulations. Makrolon® Rx1851 polycarbonate met these requirements.



Soft tissue fluid retention is a common problem during arthroscopy. A clear arthroscopic access cannula body helps in effective visualization of sutures and surgical knots. Makrolon® Rx1452 polycarbonate met the clarity and toughness requirements and exhibited excellent performance in both moldability and functionality.

# Inogen One® G2 Independent Oxygen Concentrator

## Application

The Inogen One® G2 System, a second-generation portable oxygen concentrator, offers the independence of its predecessor – plus it is 40 percent smaller, 25 percent lighter, delivers 20 percent more oxygen and a longer battery life. In fact, the Inogen One® G2 System weighs roughly three kilograms and measures 27.2 cm x 9.9 cm x 24.1 cm. Designed to be a single solution for stationary, portable, and travel oxygen therapy, the Inogen One® G2 was awarded a 2010 Industrial Designers Society of America (IDSA) Gold Design of the Decade award in the category of Solution to a Developed World Social Problem.

## Solution

The portable device's shell is constructed of six separate components molded from Bayblend® FR 3010 polycarbonate/acrylonitrile-butadiene-styrene (PC+ABS) plastic. The external battery housing is also made of three components molded from the same polycarbonate blend. Bayblend® FR 3010 plastic is a flame-retardant blend of Makrolon® polycarbonate and ABS. The blend is noted for its combination of high impact strength and good balance of high heat distortion and mechanical performance.

# First Pocket-Sized Mechanical Injection Pump: RoweMed AG RoweMiniPump

## Application

RoweMiniPump (regulatory approval pending) by RoweMed AG is the first pocket-sized mechanically driven injection pump that patients can use to administer medication themselves with optimum dosing accuracy –from chemotherapy, pain treatment and cardiology to the administration of antibiotics, corticoids, hormones and antiepileptic drugs. As a mobile device, it must be able to withstand frequent "everyday accidents", such as being dropped or hit.

## Solution

Makrolon® Rx1805 polycarbonate was ideally suited to the complex requirements of the pump, providing the high level of transparency, impact strength, resistance to medication and good sterilization properties. The individual housing components of the pump are made of Makrolon® Rx1805 polycarbonate, which can easily be joined together through laser welding. A key factor in RoweMed's decision to opt for this material was the fact that the polycarbonate can be sterilized using electron beam or gamma radiation. RoweMed also placed great emphasis on the robustness of the pump, for which Makrolon® Rx1805 polycarbonate is invaluable, thanks to its toughness.

# Handled With Care:
# Q-FLO™ Valve Connector From Infusion Innovations, Inc.

## Application

Q-FLO™ valve connector from Infusion Innovations, Inc. (I³) offers improved safety and convenience for healthcare workers administering cytotoxic drugs to patients. Q-FLO™ is approved by the U.S. Food and Drug Administration (FDA) for use in reconstituting, dispensing/transferring, administering and disposal of potentially hazardous fluids. To make this possible, the application required a material that met FDA requirements and had a proven safety and functional profile.

## Solution

I³ chose Makrolon® Rx1805 polycarbonate for use in its Q-FLO™ valve connector. The material's property profile – including strength, clarity, lipid/chemical resistance, biocompatibility and gamma stability – made it a great choice for this application. In Makrolon® Rx1805 polycarbonate, I³ found a material that met its stringent requirements to create a resilient infusion valve connector for use with cytotoxic and nuclear medicine.

# Quick Fix:
# Metric Medical Devices, Inc. Super Staple™ Classic

## Application

The Super Staple™ Classic bone fixation device is offered as a sterile, disposable, complete procedure kit. According to Metric Medical Devices, Inc., its Super Staple™ Classic provides a superior and instantaneous bone compression force required for bone healing. The bone fixation staple is pre-loaded into the easy-to-use delivery instrument.

## Solution

The housing for the bone fixation device utilizes Makrolon® Rx2530 polycarbonate. Metric Medical Devices, Inc. selected this medical grade polycarbonate for its high strength, temperature stability, clarity and biocompatibility. The material is injection molded to form the housing of the device, which is roughly the size of a syringe. Makrolon® Rx2530 polycarbonate complies with ISO-10993 and U.S. Food and Drug Administration biocompatibility guidelines. Covestro provided material selection and design assistance to Metric Medical Devices, Inc.

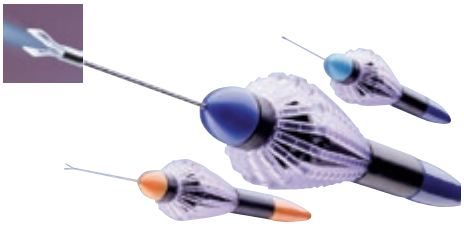
# Innovative Instruments: Alcon Grieshaber Revolution™ DSP Micro Forceps and Scissors

## Application

Alcon Grieshaber AG developed the Grieshaber Revolution™ DSP micro forceps and scissors to help combat vision-impairing retinal disease, most commonly caused through macular degeneration, or AMD. The micro forceps and scissors have an advantage over similar commercial instruments: they can be freely rotated while being used. This innovative and extremely helpful function is made possible in part by a plastic basket of thin-walled ribs that forms part of the instrument body.

## Solution

When designing the thin-walled ribs, Makrolon® 2458 polycarbonate was utilized to fill the requirements of an engineering material with strength, stiffness and toughness. The excellent dimensional stability of Makrolon® 2458 polycarbonate also makes it possible for this delicate injection-molded component to be easily demolded and for the forceps or scissors to work reliably.



# Just What The Doctor Ordered: OrthoSensor™ Knee Balancer

## Application

The OrthoSensor™ knee balancer is a revolutionary, intelligent orthopedic device used during total knee replacement surgery. It uses sensors and wireless technology to provide real-time, evidenced-based data to the surgeon to optimize the positioning and balance of implants. The device contributes to improved patient comfort and prosthetic longevity by giving surgeons the ability to quantify adjustments intraoperatively. OrthoSensor™ needed a high-quality, reliable material for this application.

## Solution

Makrolon® Rx1851 polycarbonate's compliance with FDA-modified 10993, Part 1 is a necessary characteristic for the OrthoSensor™ knee balancer. The knee balancer comes in four transparent colors – brown, green, blue and yellow – each color-matched to the customer's stipulations and each indicating a specific surgical size. The device can be used with four shim sizes that correspond to these colors and increase the thickness of the device allowing for variations in patient anatomy. The material's improved flow, lubricity, easy release and strength also led its use in this device. Covestro's ability to provide custom color formulations for its Makrolon® polycarbonate solidified the customer's choice.

# Product Overview of Medical Grades

All Makrolon® and Apec® grades are available in both transparent and opaque colors.
See the "Compounded Color Technology" section in this brochure.

**Makrolon® 2258** (MVR 34 $cm^3$ / 10 min) is a high flow polycarbonate with easy-release characteristics, good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® 2458** (MVR 19 $cm^3$ / 10 min) is an easy-flow polycarbonate with easy-release characteristics, good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® 2558** (MVR 14 $cm^3$ / 10 min) is an easy-flow polycarbonate with easy-release characteristics, good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® 2658** (MVR 12 $cm^3$ / 10 min) is a medium-viscosity polycarbonate with easy-release characteristics, good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® 2858** (MVR 9 $cm^3$ / 10 min) is a medium-viscosity polycarbonate with easy-release characteristics, good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® 3108** (MVR 6 $cm^3$ / 10 min) is a high-performance polycarbonate with good hydrolysis resistance and biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx1452** (MVR 16 $cm^3$ / 10 min) is a polycarbonate with enhanced release and surface lubricity characteristics. This resin is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx1805** (MVR 6 $cm^3$ / 10 min) is a lipid-resistant polycarbonate. It is particularly suitable for sterilization by radiation and is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx1851** (MVR 23 $cm^3$ / 10 min) high-flow polycarbonate with enhanced release and surface lubricity characteristics. This resin is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx2430** (MVR 20 $cm^3$ / 10 min) high-flow polycarbonate. It is particularly suitable for sterilization by radiation and is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx2435** (MVR 23 $cm^3$ / 10 min) high-flow polycarbonate with easy-release characteristics. It is particularly suitable for sterilization by radiation and is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx2440** (MVR 19 $cm^3$ / 10 min) high-flow polycarbonate stabilized for radiation sterilization of devices in oxygen-free packaging. This resin is biocompatible according to ISO 10993-1 test requirements.

**Makrolon® Rx2530** (MVR 15 $cm^3$ / 10 min) is a medium-viscosity polycarbonate. It is particularly suitable for sterilization by radiation and is biocompatible according to ISO 10993-1 test requirements.

**Bayblend® M750** (MVR 14 $cm^3$ / 10 min) is an opaque, non-reinforced PC+ABS blend. This resin is biocompatible according to ISO 10993-1 test requirements.

**Bayblend® M850 XF** (MVR 25 $cm^3$ / 10 min) is an opaque, high-flowing, non-reinforced PC+ABS blend. This resin is biocompatible according to ISO 10993-1 test requirements.

**Apec® 1745** (MVR 17 $cm^3$ / 10 min) is a high-heat copolycarbonate suitable for repeated steam sterilization up to 143°C. This resin has easy-release characteristics, high softening temperature and good hydrolysis resistance and is biocompatible according to ISO 10993-1 test requirements.

# With Covestro, You Have Choices Makrolon®, Bayblend® and Apec® Medical Grades

With our family of polycarbonate resins and resin blends, you can find the material that best suits the requirements of your medical device or healthcare application. These products are biocompatible per ISO 10993-1 test requirements. Below is an overview of these products and their properties. The products are available in pellet form and are typically processed by injection molding. Please refer to the charts below and on the following pages for detailed information regarding these materials.

## Medical Grades (ISO Standard 10993-1)

**Makrolon® Polycarbonate —** Our polycarbonate resin is lightweight and offers a unique combination of transparency, impact resistance and rigidity. With a range of grades to meet the needs of medical applications, Makrolon® medical grades can be sterilized by all common methods.

| Makrolon® Medical Grades | Sterilization Method | MVR ($cm^3$/10 min) | Material |
|---|---|---|---|
| | ETO & Steam Sterilization | 34 | 2258 |
| | | 23 | Rx1851 |
| | | 19 | 2458 |
| | | 14 | Rx1452 |
| | | 16 | 2558 |
| | | 12 | 2658 |
| | | 9 | 2858 |
| | | 6 | 3108 |
| | Gamma, e-Beam, ETO & Steam Sterilization | 23 | Rx2435 |
| | | 20 | Rx2430 |
| | | 15 | Rx2530 |
| | | 6 | Rx1805 |
| | Gamma, e-Beam in $O_2$-free environments, ETO & Steam Sterilization | 19 | Rx2440 |

NOTE: Transparent, translucent, or opaque colors that meet the testing requirements of FDA-Modified ISO 10993-1 are available.

**Apec® High-Heat Polycarbonate —** This material is characterized by its high transparency, toughness and strength with a higher heat resistance compared to Makrolon®. It is suitable for limited reuse after high-heat steam autoclaving up to 143°C.

| Apec® Medical Grade | Sterilization Method | MVR ($cm^3$/10 min) | Material |
|---|---|---|---|
| | Gamma, e-Beam, ETO & Steam Sterilization | 17 | 1745 |

NOTE: Transparent, translucent, or opaque colors that meet the testing requirements of FDA-Modified ISO 10993-1 are available.

Bayblend® PC+ABS Blend —These opaque resins are blends of polycarbonate (PC) and acrylonitrile butadiene styrene polymer (ABS) that offer an excellent combination of mechanical and thermal properties, exhibiting high toughness, rigidity, dimensional stability and easy processing.

| Bayblend® Medical Grades | Sterilization Method | MVR ($cm^3$/10 min) | Material |
|---|---|---|---|
| | Gamma, e-Beam, ETO Sterilization | 25 | M850 XF |
| | | 14 | M750 |

NOTE: Colors that meet the testing requirements of FDA-Modified ISO 10993-1 are available.

# With Covestro, You Have Choices
# Bayblend® and Makroblend® for Electromechanical Devices

## Standard Grades

Flame-retardant Bayblend® and Makroblend® grades are used in applications such as device housings where flame-retardancy is needed, yet ISO 10993-1 biocompatibility is not required. Makroblend® is a semi-crystalline blend of PC with a polyester that combines the outstanding characteristics of both polymers to create ultra-tough materials that meet demanding physical, chemical and environmental requirements.

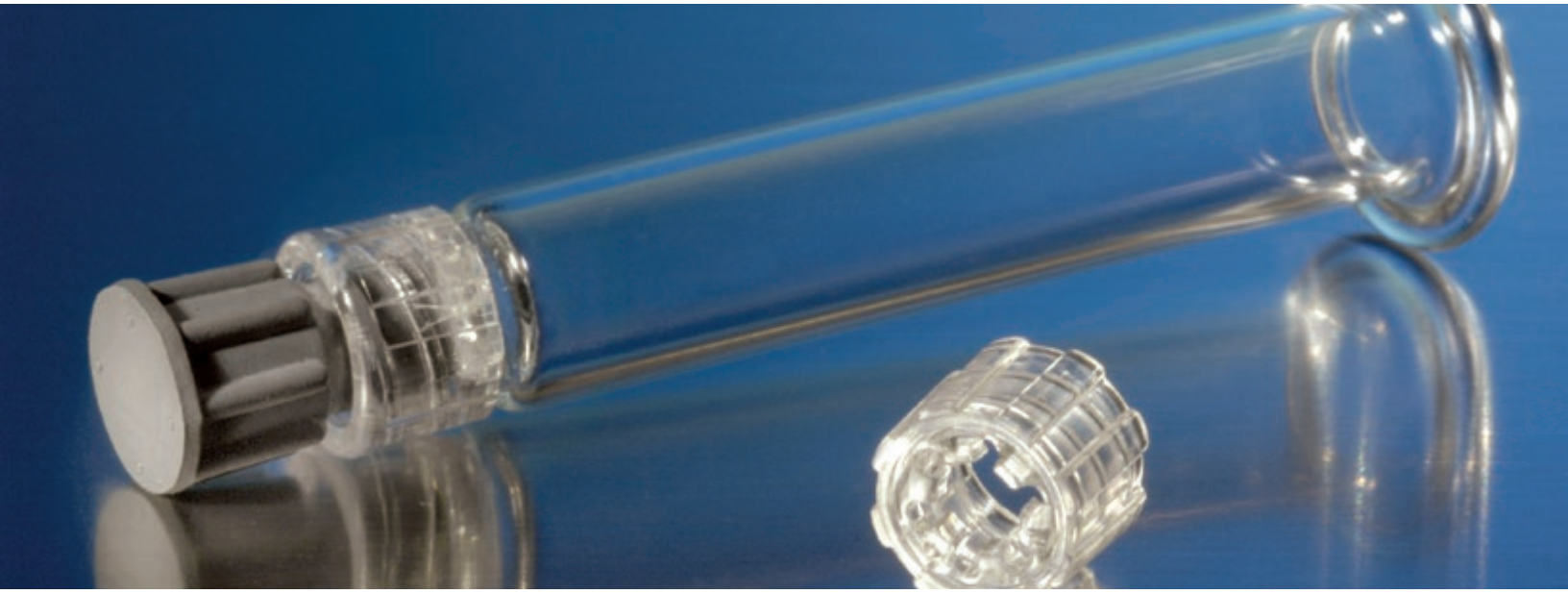
| Grade | Description |
|---|---|
| Bayblend® FR3010 | Flame-retardant (non-halogenated) / PC+ABS |
| Makroblend® EL700 | Flame-retardant / Chemically resistant/ PC+Polyester |
| Makroblend® EL703 | Flame-retardant / UV stable / Chemically resistant/ PC+Polyester |
| Makroblend® EC150 | Flame-retardant (non-halogenated) / Chemically resistant / PC+Polyester |
| Makroblend® M4000 FR | Flame-retardant / Superior chemical resistance / PC+Polyester |

## Limited Biocompatibility Grades

For medical devices with housings that are in contact with intact skin, Bayblend® M301 FR and Makroblend® M525 for injection molding and Bayblend® M303 FR for extrusion have met the testing requirements of ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization) standards in particular colors. Additional colors which utilize biocompatibility-tested colorants can be formulated. Only products that meet these requirements may be considered candidates for applications contacting intact skin.

| Grade | Description |
|---|---|
| Bayblend® M301 FR | Flame-retardant (non-halogenated) / Injection Molding / PC+ABS |
| Bayblend® M303 FR | Flame-retardant (non-halogenated) / Extrusion / PC+ABS |
| Makroblend® M525 | Chemically resistant / Injection Molding / PC+Polyester |

# Physical and Chemical Properties



## Thermal Properties

Makrolon®, Bayblend®, Apec® and Makroblend® resins are noted for their high heat resistance and dimensional stability. At low loading levels, parts molded from them resist deformation at temperatures up to:

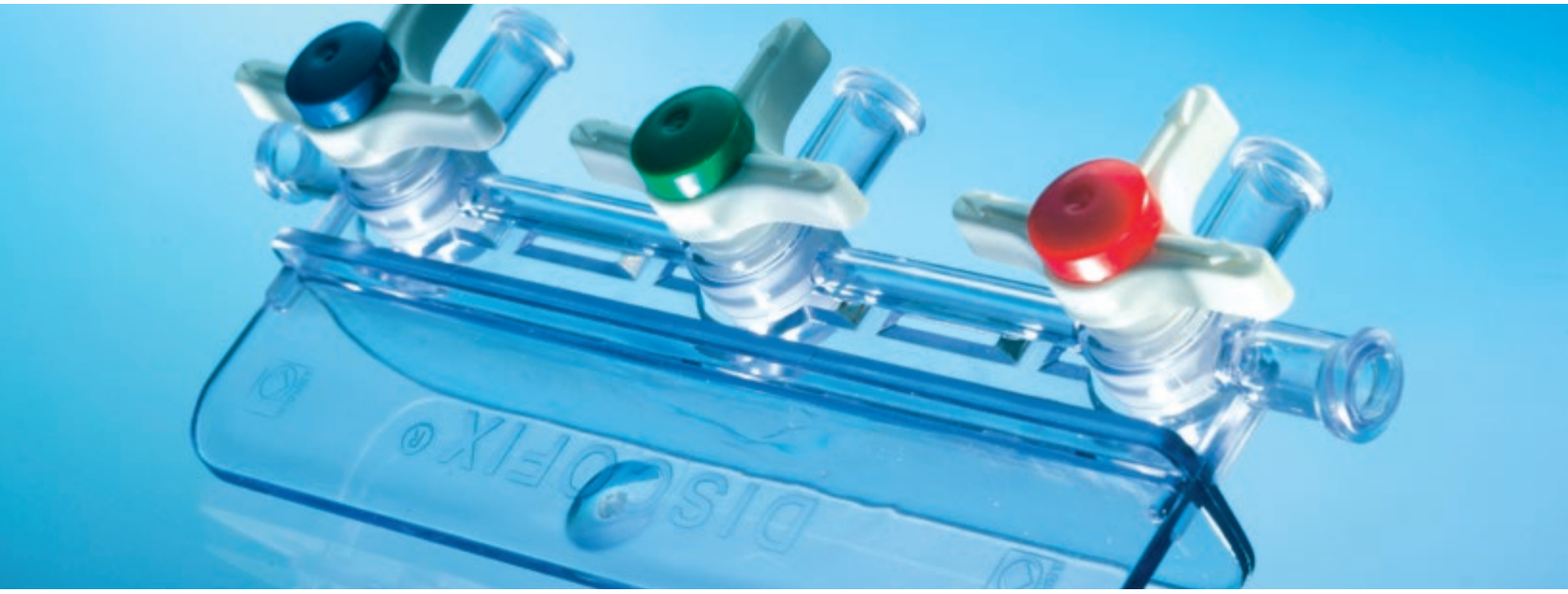
- 120°C for Bayblend®
- 135°C for Makrolon®
- 160°C for Apec®

Approximately 10°C above these temperatures, molded parts begin to soften and become more susceptible to deformation. Makrolon® assumes what can be considered a molten state at temperatures above approximately 220°C. For Apec® 1745, this occurs at about 240°C, while Bayblend® resins achieve this state at about 200°C. Makroblend® melting temperatures depend on the polyester component (i.e. PET or PBT) and achieve a melted state at about 225°C for PC+PBT and 265°C for PC+PET. Even higher temperatures are required, however, before the materials attain adequate flowability for processing on injection molding machines and extruders. Lengthy periods of heating to temperatures above the grade's recommended processing temperature can lead to thermal decomposition, a reduction in mechanical performance and cosmetic defects such as discoloration and splay.

When these materials are subjected to temperatures in excess of about 80°C for long periods of time, a structural change might occur which could be characterized by a slight increase in the tensile and flexural strengths and a reduction of the notched impact strength. In addition, depending on the grade and how parts made of Makroblend® were processed, additional shrinkage due to further crystallization of the polyester may occur.

The maximum permitted service temperature for parts made of Makrolon®, Bayblend®, Apec® and Makroblend® grades depend on part geometry, the type of loading and on the part performance requirements. The temperature indices to IEC 60216-1 and UL 746 B can be regarded as practical reference values for the maximum temperatures during long-term service. When a component is subjected to high temperature and mechanical loading simultaneously, creep behavior must be taken into account. Our website explains how to account for creep in part design. Isochronous stress-strain curves used in creep calculations can be found in the CAMPUS® database.

# Physical and Chemical Properties



## Optical and Weathering Properties

Optically transparent Makrolon® parts have a refractive index nD20 of 1.586. Apec® 1745 has a refractive index nD20 of 1.578. The virtually colorless, transparent grades demonstrate light transmission of up to 89% in the visible range. Ultraviolet light, by contrast, is absorbed and leads to discoloration and a reduction in the impact strength over the course of time. Parts molded from medical grades of Makrolon®, Bayblend®, Makroblend® and Apec® are not UV protected and are therefore not suitable for long-term outdoor exposure without a protective coating.

Further technical information on Makrolon®, Bayblend®, Apec® and Makroblend® is available at www.plastics.covestro.com.

## Behavior Towards Moisture (Hydrolysis Resistance)

Molded parts made of Apec®, Bayblend®, Makrolon® or Makroblend® mentioned in this brochure absorb as much as 0.2% moisture at room temperature and 50% relative humidity. Absorption rises to only about 0.5% with immersion in water at ambient temperature. The physical and dimensional properties remain virtually unaffected by this slight absorption. For example, molded parts made of Makrolon® may be cleaned many times with hot water in common household dishwashers. The possible lifetime of a molded part depends on the material grade, color, processing conditions and part geometry. While certain Makrolon® grades can be washed thousands of times in hot water (for further information see our technical information sheet "Cleaning, disinfection and sterilization of Makrolon® articles" at www.plastics.covestro.com), permanent exposure to water at temperatures in excess of 60°C is not recommended for Makrolon®, Bayblend®, Apec®, or Makroblend® since hot water causes gradual chemical degradation. This may affect the optical and mechanical properties of the part. The impact strength, notched impact strength and tensile strain at break can decrease in environments that can promote hydrolysis such as those involving lengthy contact with hot water or hot and humid environments.

# Processing

## Drying of the Resin

Makrolon®, Bayblend®, Apec® and Makroblend® must be dried prior to processing. For injection molding of Makrolon®, Bayblend® and Apec®, no more than 0.02% residual moisture may be present in the pellets. Moisture levels of the resin must not exceed 0.01% when molding Makroblend® or when extruding any of these resins. Moisture in the melt can lead to surface defects and an excessive reduction in molecular weight and part performance. All resins should be dried in suitable dryers.

The optimal drying conditions will depend on the resin and equipment used. We recommend a drying temperature of 90°C for most grades of Bayblend®, 100°C for PC+PBT Makroblend®,110°C for PC+PET Makroblend®, 120°C for Makrolon® and 130°C for Apec® grades. The drying time is largely a function of the nature, type and capacity of the drying unit and can range from 4 to 12 hours. A drying time of 4 hours is usually sufficient in modern dry-air dryers. One method of dispensing with pre-drying is for the moisture to be removed during melting with the aid of a degassing unit, as has been standard practice in extrusion for a long time. Additional information about drying our thermoplastic resins is available for download at www.plastics.covestro.com.

## Injection Molding

Makrolon®, Bayblend®, Apec® and Makroblend® can be processed on all modern injection molding machines including those with or without shut-off nozzles. The press barrel should be equipped with a free-flowing, sliding-check-ring style non-return valve. Open nozzles require relatively large flow channel diameters, especially those for Apec® molding. If there is a slight leakage of melt, this can generally be prevented by retracting the screw somewhat to relieve pressure.

Unfilled grades of these resins exhibit nearly uniform shrinkage in the flow and cross-flow directions. Molding shrinkage varies by grade, part geometry and processing conditions but is typically 0.5 to 0.8% for Makrolon® and Bayblend®, about 0.8% for Makroblend® and 0.7 to 0.9% for Apec®. Consult the published shrink rate for each grade. The processing melt temperatures typically range between 280 and 320°C for Makrolon®, 250 and 275°C for Bayblend®, 260 and 290°C for Makroblend® and 320 and 340°C for Apec®. Excessively high processing temperatures and/or long residence times in the press barrel or hot runner can damage the material and lead to a reduction in part toughness and to surface defects in the form of streaks or discoloration.

# Processing

To ensure parts with low inherent stress and good surface cosmetics, the mold must provide uniform cooling and be capable of maintaining mold temperatures of at least 80–120°C for Makrolon®, 70–100°C for Bayblend®, 70–100°C for Makroblend® and 110–130°C for Apec®. These materials seldom require external mold release agents and normally release adequately from molds with 1 ˚ of draft. Apec® resins are an exception, requiring 2 ˚ to 3 ˚ of draft to prevent ejection damage or induced stresses during demolding.

Even under the recommended processing conditions, small quantities of decomposition product may be released during processing. To preclude any risk to the health and well-being of the machine operators, provisions for efficient exhaust ventilation and fresh air makeup must be provided at the workplace in accordance with the Safety Data Sheet. In order to prevent the partial decomposition of the polymer and the generation of volatile decomposition products, the prescribed processing temperatures should not be substantially exceeded.

Several brochures and guides with additional information about injection molding Makrolon®, Bayblend®, Makroblend® and Apec® are available for download from www.plastics.covestro.com.

## Extrusion

Among the products described in this brochure, only Bayblend® M303 FR is specifically designed for processing by extrusion in either sheet or profiles. Medical grades of Makrolon®, Bayblend®, Makroblend® and Apec® can be processed on extruders in exceptional cases. Among medical grade Makrolon® resins, higher-viscosity grades such as Makrolon® 3108 and Rx1805 offer best results due to their higher viscosity and greater melt-strength.

## Determination of Internal Stress Levels

Inherent stresses develop in Makrolon® moldings as a result of the molding process and subsequent cooling. In plastics that undergo pronounced relaxation, these inherent stresses disappear over time without any significant change in the shape of the moldings. Plastics that only undergo limited relaxation are less able to eliminate these stresses. The amorphous plastics Makrolon®, Bayblend®, Apec® and Makroblend® belong to the latter class because of their low tendency to creep under load. The internal stresses are largely retained inside these plastics and are then

superimposed onto the external service stresses. Both compressive stresses and tensile stresses occur as a function of the molded part geometry, material flow and cooling characteristics. If excessive tensile stresses prevail, this can lead to local deformation zones in the surface and the formation of micro-cracks or crazes that weaken the part.

Certain chemicals also lead to crazing of Makrolon®, Bayblend®, Apec® and Makroblend®. Parts with elevated molded-in (internal) stresses and/or high applied (external) stresses are less resistant to chemical attack and the effects of moisture. It is possible to use test fluids to quickly estimate the level of molded-in stresses in Makrolon® moldings. After a timed immersion in the test fluid, the molding will exhibit visible cracks in areas where the stresses exceed the calibrated stress threshold of the test fluid. A detailed description is given in our technical information sheet "Stress crack test – Makrolon® moldings" available at www.plastics.covestro.com.

# Post-Treatment of Molded Parts

## Machining and Polishing

Injection molded parts made of Makrolon®, Bayblend®, Apec® and Makroblend® can be easily machined if the proper cutters and cutting fluids are used. There is only a low tendency towards "smearing" due to the high softening temperature of these materials. Only air or clean water should be used as cooling agents during machining. Makrolon®, Bayblend®, Apec® and Makroblend® components can be readily polished to a high gloss. Only alkali-free polishing pastes may be used, however, in order to prevent any chemical damage to the surface. The industry supplies products for painting, printing and embossing which are specially tailored to polycarbonate. Makrolon®, Bayblend®, Apec® and Makroblend® components can be vacuum metalized to a mirror-like finish.

## Joining Techniques

Detailed information on joining parts made from Makrolon®, Bayblend®, Makroblend® and Apec® is available in a guide titled "Engineering Polymers Joining Techniques" which is available for download from www.plastics.covestro.com.

Even when following recommended guidelines, it is important to test the suitability of a given joining technique. For parts requiring solvent-bonding, solvents such as methylene chloride (dichloromethane) or tetrahydrofuran (THF) are known to be suitable for polycarbonate and other resins. These solvents work by partially dissolving the contact surfaces. It is important to consult the solvents' Safety Data Sheet (SDS).

Many adhesives are suitable for Makrolon®, Bayblend®, Makroblend® and Apec®. Information is available in the "Engineering Polymers Joining Techniques" as well as from the adhesive suppliers' technical literature. Two-part adhesives, such as those based on epoxy resin, silicone (with an amine-free hardening agent) or polyurethane, are suitable both for gluing parts made of Makrolon®, Bayblend® and Apec® to one another and for gluing parts in Makrolon®, Bayblend® and Apec® to other materials. A condition for the use of adhesives based on epoxy resin, silicone and polyurethane is that these must not contain any components that are incompatible with Makrolon®, Bayblend®, Apec® and Makroblend® resins.

These resins can also be welded by means of vibration, friction, heated tool or hot gas welding. Ultra-sonic welding and heat welding are the preferred processes.

The table below summarizes our own findings with the suitability of various joining techniques and post-treatments with our resins. For more detailed information, consult our guide titled "Engineering Polymers Joining Techniques" available on our website.

| Polymer | Snap Fits | Molded-in Inserts | Solvent Bonding | Adhesive Bonding | Vibration Welding | Ultrasonic Welding | Thermal Welding |
|---|---|---|---|---|---|---|---|
| Makrolon® PC | ■ | ● | ■ | ■ | ■ | ■ | ■ |
| Apec® High-Heat PC | ■ | ● | ■ | ■ | ■ | ■ | ■ |
| Makroblend® PC+Polyester | ■ | ▲ | ▲ | ■ | ■ | ■ | ■ |
| Bayblend® PC+ABS | ■ | ● | ■ | ■ | ■ | ■ | ■ |

Key: ■ = Excellent; ▲ = Fair; ● = Poor

# Cleaning, Disinfection and Sterilization Methods for Makrolon®, Bayblend® and Apec® Parts

## Cleaning and Disinfection

Molded parts in Makrolon®, Bayblend® and Apec® can be cleaned and disinfected by almost any of the well-known methods employed in practice. However, under certain conditions contact with cleaning, disinfecting and sterilizing media may inflict some damage to the material, which could manifest itself in the form of stress cracking. A detailed description of cleaning and disinfection guidelines is provided in our technical bulletin "Cleaning, disinfection and sterilization of Makrolon® articles" at www.plastics.covestro.com.

## Sterilization

Medical devices typically require sterilization before use. There are three sterilization methods prevalent in the medical industry:

- Heat (both steam autoclave and, to a lesser extent, dry heat)
- Ethylene oxide (ETO) gas
- Irradiation with high-energy radiation (gamma or electron beam)

The table below shows which Makrolon®, Bayblend® or Apec® grades are suitable for each sterilization method. However, the resistance to the different sterilization methods and the number of sterilization cycles a medical device can withstand will vary depending upon the type/grade of Makrolon®, Bayblend® and Apec®, part design, processing parameters and other factors. The manufacturer of the medical device must check the suitability of the sterilization method in each individual case.

| Sterilization method | Makrolon® 2258, 2458, 2558, 2658, 2858, 3108, Rx1851, Rx1452 | Makrolon® Rx1805, Rx2430, Rx2435, Rx2440, Rx2530 | Apec® 1745 | Bayblend® M750, M850 XF |
|---|---|---|---|---|
| Ethylene oxide | Yes | Yes | Yes | Yes |
| Steam 121 °C | Yes | Yes | Yes | No |
| Steam 134 °C | No | No | Yes | No |
| Steam 143 °C | No | No | Yes | No |
| Hot air | Yes | Yes | Yes | No |
| Gamma radiation | (Yes)[1] | Yes | (Yes)[1] | (Yes)[1] |
| Electron beam | (Yes)[1] | Yes | (Yes)[1] | (Yes)[1] |

1. See remarks under "Sterilization with high-energy radiation"

# Sterilization

## Sterilization by steam (saturated steam)

The sterilization temperature should not exceed 125°C for Makrolon®, otherwise the molded parts can become deformed. Parts made of Apec® 1745 may be sterilized in steam up to 143°C. Care must also be taken to ensure that the Makrolon® or Apec® part is not damaged by any substances added to the boiler feed water, such as alkaline corrosion inhibitors, and that the article is positioned correctly so that no condensation can accumulate inside it. As a rule, it is possible to sterilize molded parts made of Makrolon® and Apec® many times before gradual chemical decomposition reduces the mechanical strength to a level where it is no longer adequate for certain applications. Sterilization tests on test specimens have shown that even after 100 cycles of 30 minutes each at 120 to 125°C, the part still retains comparatively good impact strength. Medical articles made of Makrolon® or Apec® which are intended for single use are not suitable for multiple use.

## Sterilization with ethylene oxide (ETO)

Suitable sterilization processes are those which use ethylene oxide, either undiluted or mixed with carbon dioxide or inert gases in the ratio 10 to 20% ethylene oxide: 90 to 80% remainder.

The temperature should not exceed 65°C during sterilization. Tests have shown that frequent sterilization can lead to slight brittleness and crack formation. Tests carried out on specimens treated with pure ethylene oxide at 55°C showed that, after 50 cycles of 6 hours each, the impact strength is unchanged compared with the starting level despite slight crack formation.

## Sterilization with high-energy radiation (gamma radiation, e-beam)

Makrolon® and Apec® have a high resistance to the effects of high-energy radiation. Assuming that 28 kGy of energy is required to sterilize Makrolon® or Apec®, the resin can be sterilized 10 to 20 times before any appreciable reduction in mechanical strength occurs. Makrolon® and Apec®, however, become more yellow with each sterilization cycle. Makrolon® Rx1805, Rx2430, Rx2435, Rx2440 and Rx2530 are high-energy radiation stable grades. The color of these grades shifts to a neutral tint after sterilization with high-energy radiation. Makrolon® Rx2440 has been designed for devices sterilized by radiation in oxygen-free packaging. Parts made from Bayblend® or Makroblend® can become more yellow and exhibit decreased impact resistance after sterilization with high-energy radiation.

# Chemical Resistance

Parts molded from Makrolon®, Bayblend®, Apec® and Makroblend® are resistant to mineral acids, including a large number of organic acids (e.g. carbonic acid, lactic acid, oleic acid and citric acid), to oxidizing and reducing agents, neutral and acidic saline solutions, a range of greases and oils, saturated aliphatic and cycloaliphatic hydrocarbons and also alcohols, with the exception of methyl alcohol. Makrolon®, Bayblend®, Apec® and Makroblend® are destroyed by alkaline/caustic solutions, ammonia gas and its solution and amines. Makrolon®, Bayblend®, Apec® and Makroblend® will dissolve in a number of industrial solvents such as dichloromethane or tetrahydrofuran (THF). Other organic compounds, such as benzene or acetone, cause them to swell. A number of chemical substances may cause stress cracking. Chemical resistance depends both on the internal molded-in stresses and on the external stresses to which the part is exposed (see "Stress crack test – Makrolon® moldings" under www.plastics.covestro.com). In the case of Makrolon®, the higher-viscosity grades generally offer better resistance to chemicals. Makroblend® grades can provide even higher levels of chemical resistance.

The tables which follow list test results after exposure to various chemicals typically encountered in medical environments. Exposure conditions were 24 hours at 23°C. The ratings are based on strain-limit testing described in the Covestro publication "Chemical Compatibility Test for Unreinforced Thermoplastic Resins", available online. Results show behavior af strains up to 1%. As is the case with any compatibility test, the results are dependent on such variables as concentration, time, temperature, part design and residual stresses, and should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions prior to commercial use.

## Resins for Medical Devices

Medical devices often come into contact with a variety of substances from medical tubing, drugs, IV-fluids and antiseptics.

The table below summarizes the resistance of medical grade products to examples of these media.

| Media | Makrolon® Rx1805 | Makrolon® Rx2530 | Makrolon® 2858 | Apec® 1745 |
|---|---|---|---|---|
| Dioctyl Phthalate | ▲ | ▲ | ▲ | ▲ |
| Trioctyl Trimellitate | ■ | ▲ | ■ | ▲ |
| 20% Lipid Emulsion | ■ | ▲ | ▲ | ▲ |
| 1% Saline Solution | ■ | ■ | ■ | ■ |
| Deionized water | ■ | ■ | ■ | ■ |
| Isopropyl alcohol (70%) | ■ | ▲ | ▲ | ▲ |
| Betadine[1] | ■ | ■ | ■ | ■ |
| 3% Hydrogen Peroxide | ■ | ■ | ■ | ▲ |

Key: ■ = Resistant; ▲ = Limited Resistance; ● = Poor Resistance

**1. Betadine is a trademark of Purdue Products L.P.**

# Chemical Resistance

## Resins for Electromechanical Housings

Housings come into contact with a greater variety of substances than medical devices. In addition to media described in the table on the previous page, wearable devices are often in contact with skin lotions or detergents. Equipment housings are often cleaned with disinfectants. The table below summarizes the resistance of our resins for electro-mechanical devices to various substances.

| Media | Bayblend® M301 FR | Bayblend® M850 XF and M750 | Makroblend® M525 | Makroblend® EC150 | Makroblend® EL700 | Makroblend® M4000 FR |
|---|---|---|---|---|---|---|
| Skin Lotion | ● | ■ | ■ | ■ | ■ | ■ |
| Isopropyl alcohol (70%) | ▲ | ■ | ■ | ▲ | ▲ | ■ |
| Betadine[1] | ■ | ■ | ■ | ■ | ■ | ■ |
| 10% Bleach | ▲ | ■ | ■ | ■ | ▲ | ■ |
| Bleach, full strength | ▲ | ■ | ■ | ■ | ▲ | ■ |
| 2% Glutaraldehyde | ▲ | ▲ | ▲ | ■ | ■ | ■ |
| 3% Hydrogen Peroxide | ▲ | ■ | ■ | ■ | ▲ | ■ |

Key: ■ = Resistant; ▲ = Limited Resistance; ● = Poor Resistance

# Compounded Color Technology

The innovative line of compounded (pre-colored) colors and special effects from Covestro allow industrial designers to break the barriers of historical colors that could be constraining when developing new medical device and healthcare applications.

To assist with new product development, custom-colored products in quantities down to 25kg, are available.

## Medical Colors

Our colors and special effects for medical grades allow differentiation of applications and branding. Medical colors for Makrolon®, Apec® and Bayblend® medical grades and limited compatibility grades have met certain testing requirements of FDA-Modified ISO 10993-1.

# Covestro Medical Grades and Regulatory Information

## Guidance on use of Covestro products in a Medical Application

All Covestro thermoplastics, sheets, and films (herein after "products") that are designated as "Medical Grade" meet certain biocompatibility test requirements of USP Plastics Class VI and ISO 10993-1 (table below) for the categories including:

(1) skin contact

(2) up to 24 hours contact with circulating blood, tissue, bone, and dentin

(3) up to 30 days contact with mucosal membranes, compromised surfaces, and blood path, indirect.

These tests are conducted under Good Laboratory Practices as defined by the FDA in 21 CFR Part 58. These products were sterilized by ethylene oxide and gamma radiation prior to testing. Only these products may be considered candidates for applications requiring biocompatibility. No "Medical Grade" product will be available for sale until successful completion of testing.

"Medical Application" means all applications of medical devices wherein the medical device is manufactured with a Covestro product(s) and is intended under normal use to be brought into direct contact with the patient's body (e.g., skin, body fluids or tissues, including indirect contact to blood).

Covestro products designated as "Medical Grade" shall not be considered candidates for the following types of Medical Applications unless Covestro explicitly agrees, in writing, to sell such products for such applications:

(a) cosmetic, reconstructive, or reproductive implant applications

(b) any other long-term implant applications

(c) applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days

(d) applications having greater than 24 hours contact with circulating blood, tissue, bone and dentin.

The biocompatibility testing referenced above cannot assure the biocompatibility of final or intermediate products made from Covestro products or the suitability of such products for their use in a Medical Application, i.e., the test data cannot be used to conclude that any medical devices manufactured from the Covestro products meet the necessary requirements of ISO Standard 10993-1. It is the sole responsibility of the manufacturer of final end-use product to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements.

### "Biological Evaluation of Medical Devices" selected tests include:

1. Cytotoxicity
2. Kligman Maximization
3. Intracutaneous Injection
4. Systemic Toxicity
5. Pyrogenicity
6. Ames Reverse Mutation
7. Muscle Implantation
8. Hemolysis – Direct and Indirect
9. In-vitro Hemocompatibility
10. USP Physicochemical Test
11. Heavy Metals Analysis – Acid Digest and Extraction

# Covestro Medical Grades and Regulatory Information

The designation as "Medical Grade" does not mean that Covestro has determined the product is suitable for use in any particular Medical Application. Covestro makes no representations regarding the suitability of a Covestro product for a particular Medical Application or final end-use product.

A determination that the Covestro product is suitable for use in a particular Medical Application or final end-use product can only be made by the purchaser of the Covestro product who utilizes it in a Medical Application and conducts all necessary testing and evaluation to support such a determination.

Only virgin Medical Grade Covestro products have been tested according to these tests under ISO 10993-1. Any use of regrind for example, runners from mold flow channels or trim pieces, must be evaluated by the medical device manufacturer for suitability.

## Appropriate use of Covestro Products in a Medical Application

Covestro has not performed clinical medical studies concerning the use of Covestro products. Moreover, Covestro has neither sought nor received approval from the United States Food and Drug Administration (FDA) or other competent authorities from other regions for the use of Covestro products in a Medical Application. Covestro makes no representations or warranty regarding (and accepts no responsibility for determining) either: (a) the suitability of a Covestro product for a particular Medical Application or final end-use product or (b) the adequacy of any warning relating to a Covestro product or particular Medical Application or final end-use product.

The suitability of a Covestro product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, method of manufacture, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final end-use product to determine the suitability (including biocompatibility) of all raw materials and components, including any Covestro products, in order to ensure that the final product:

- meets relevant biocompatibility requirements and is otherwise safe for its end-use
- performs or functions as intended
- is suitable for its intended use
- complies with all applicable FDA and other regulatory requirements.

It also is the sole responsibility of the manufacturer of the final end-use product to conduct all necessary tests and inspections and to evaluate the final product under actual end-use requirements and to adequately advise and warn purchasers, users and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any post-market surveillance obligations.

Any decision regarding the appropriateness of a particular medical product in a particular clinical or Medical Application should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician. Covestro cannot weigh the benefits against the risks of a medical device and cannot offer a medical or legal judgment on the safety or efficacy of the use of a Covestro product in a specific Medical Application.

# Typical Product Values

# Makrolon® Typical Values

Makrolon®

| | | | | | Medical | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Properties | | Test Standard | Test Condition | Units | Rx1851* | Rx2435 | Rx2430 | Rx2440 | Rx1452* | Rx2530 | Rx1805 |
| **Rheological Properties** | | | | | | | | | | | |
| C | Melt Volume Rate | ISO 1133 | 300°C/1.2 kg | $cm^3$/10min | 23 | 23 | 19 | 19 | 16 | 15 | 6.0 |
| C | Molding Shrinkage, Parallel | ISO 294-4 | 60x60x2mm; 500 bar | % | 0.70 | 0.65 | 0.60 | 0.60 | 0.70 | 0.60 | 0.70 |
| C | Molding Shrinkage, Normal | ISO 294-4 | 60x60x2mm; 500 bar | % | 0.70 | 0.65 | 0.65 | 0.65 | 0.70 | 0.65 | 0.70 |
| **Mechanical Properties** | | | | | | | | | | | |
| C | Tensile Modulus | ISO 527-1, -2 | 1 mm/min | MPa | 2400 | 2400 | 2400 | 2400 | 2400 | 2400 | 2400 |
| C | Yield Stress | ISO 527-1, -2 | 50 mm/min | MPa | 65 | 67 | 67 | 67 | 68 | 67 | 67 |
| C | Yield Strain | ISO 527-1, -2 | 50 mm/min | % | 6.0 | 6.1 | 6.1 | 6.1 | 6.0 | 6.1 | 6.3 |
| C | Nominal Strain at break | ISO 527-1, -2 | 50 mm/min | % | >50 | >50 | >50 | >50 | >50 | >50 | >50 |
| | Flexural Modulus | ISO 178 | 2 mm/min | MPa | 2400 | 2400 | 2400 | 2400 | 2400 | 2400 | 2400 |
| | Flexural Strength | ISO 178 | 2 mm/min | MPa | 98 | 100 | 100 | 100 | 100 | 100 | 98 |
| | Flexural Stress at 3.5% Strain | ISO 178 | 2 mm/min | MPa | 76 | 74 | 74 | 74 | 78 | 74 | 73 |
| C | Charpy Impact Strength** | ISO 179-1eU | 23°C | $kJ/m^2$ | N | N | N | N | N | N | N |
| C | Charpy Impact Strength** | ISO 179-1eU | -30°C | $kJ/m^2$ | N | N | N | N | N | N | N |
| | Charpy Notched Impact Strength** | ISO 7391 b.o. 179-1eA | 23°C, 3 mm | $kJ/m^2$ | | 75P(C) | 70P(C) | 75P(C) | | 70P | 80P |
| | Charpy Notched Impact Strength** | ISO 7391 b.o. 179-1eA | -30°C, 3 mm | $kJ/m^2$ | | 12C | 14C | 12C | | 14C | 16C |
| | Izod Notched Impact Strength** | b.o. ISO 180-A | 23°C, 3.2 mm | $kJ/m^2$ | 65P | 75P(C) | 80P(C) | 75P(C) | | 80P(C) | 90P(C) |
| | Izod Notched Impact Strength** | b.o. ISO 180-A | -30°C, 3.2 mm | $kJ/m^2$ | | 12C | 12C | 12C | | 12C | 14C |
| C | Puncture Maximum Force | ISO 6603-2 | 23°C | N | 5200 | 5100 | 5300 | 5100 | 5300 | 5300 | 5700 |
| C | Puncture Energy | ISO 6603-2 | 23°C | J | 55 | 55 | 60 | 55 | 60 | 60 | 65 |
| C | Puncture Maximum Force | ISO 6603-2 | -30°C | N | 6200 | 6000 | 6200 | 6000 | 6200 | 6200 | 6600 |
| C | Puncture Energy | ISO 6603-2 | -30°C | J | 65 | 65 | 70 | 65 | 65 | 70 | 70 |
| | Ball Indentation Hardness | ISO 2039-1 | | $N/mm^2$ | 117 | 118 | 118 | 118 | 118 | 118 | 114 |
| **Thermal Properties** | | | | | | | | | | | |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 1.80 MPa | °C | 121 | 120 | 122 | 120 | 120 | 122 | 126 |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 0.45 MPa | °C | 134 | 132 | 134 | 132 | 132 | 134 | 138 |
| | Vicat Softening Temperature | ISO 306 | 50 N; 120°C/h | °C | 142 | 140 | 142 | 140 | 141 | 142 | 145 |
| | Resistance to heat (ball pressure test) | IEC 60695-10-2 | | °C | 135 | 132 | 132 | 132 | 132 | 132 | 135 |
| C | Coefficient of Linear Thermal Expansion, Parallel | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 |
| C | Coefficient of Linear Thermal Expansion, Transverse | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 |
| **Other Properties** | | | | | | | | | | | |
| C | Water Absorption (saturation value) | ISO 62 | Water at 23°C | % | 0.30 | 0.30 | 0.30 | 0.30 | 0.30 | 0.30 | 0.30 |
| C | Water Absorption (equilibrium value) | ISO 62 | 23°C; 50% r.h. | % | 0.12 | 0.12 | 0.12 | 0.12 | 0.12 | 0.12 | 0.12 |
| C | Density | ISO 1183-1 | | $kg/m^3$ | 1200 | 1200 | 1200 | 1200 | 1200 | 1200 | 1200 |
| | Injection molding – melt temperature | ISO 294 | | °C | 280 | 280 | 280 | 280 | 280 | 280 | 300 |
| | Injection molding – mold temperature | ISO 294 | | °C | 80 | 80 | 80 | 80 | 80 | 80 | 80 |
| | Injection molding – injection velocity | ISO 294 | | mm/s | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

* - Only available in North America, as of Sept. 1, 2015.

**C** - These property characteristics are taken from the CAMPUS® plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

**Impact properties: N = non-break, P = partial break, C = complete break

# Makrolon® Typical Values

Makrolon®

| | | | | | Medical | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Properties | | Test Standard | Test Condition | Units | 2258 | 2458 | 2558 | 2658 | 2858 | 3108 |
| **Rheological Properties** | | | | | | | | | | |
| C | Melt Volume Rate | ISO 1133 | 300°C/1.2 kg | $cm^3$/10min | 34 | 19 | 14 | 12 | 9.0 | 6.0 |
| C | Molding Shrinkage, Parallel | ISO 294-4 | 60x60x2mm; 500 bar | % | 0.65 | 0.65 | 0.65 | 0.70 | 0.70 | 0.70 |
| C | Molding Shrinkage, Normal | ISO 294-4 | 60x60x2mm; 500 bar | % | 0.65 | 0.70 | 0.70 | 0.75 | 0.75 | 0.75 |
| **Mechanical Properties** | | | | | | | | | | |
| C | Tensile Modulus | ISO 527-1, -2 | 1 mm/min | MPa | 2400 | 2400 | 2400 | 2400 | 2400 | 2400 |
| C | Yield Stress | ISO 527-1, -2 | 50 mm/min | MPa | 65 | 65 | 66 | 66 | 66 | 65 |
| C | Yield Strain | ISO 527-1, -2 | 50 mm/min | % | 6.0 | 6.1 | 6.1 | 6.1 | 6.1 | 6.3 |
| C | Nominal Strain at break | ISO 527-1, -2 | 50 mm/min | % | >50 | >50 | >50 | >50 | >50 | >50 |
| | Flexural Modulus | ISO 178 | 2 mm/min | MPa | 2350 | 2350 | 2400 | 2400 | 2400 | 2350 |
| | Flexural Strength | ISO 178 | 2 mm/min | MPa | 97 | 97 | 97 | 97 | 97 | 96 |
| | Flexural Stress at 3.5% Strain | ISO 178 | 2 mm/min | MPa | 73 | 73 | 73 | 73 | 73 | 72 |
| C | Charpy Impact Strength** | ISO 179-1eU | 23°C | $kJ/m^2$ | N | N | N | N | N | N |
| C | Charpy Impact Strength** | ISO 179-1eU | -30°C | $kJ/m^2$ | N | N | N | N | N | N |
| | Charpy Notched Impact Strength** | ISO 7391 b.o. 179-1eA | 23°C, 3 mm | $kJ/m^2$ | 55P | 65P | 70P | 70P | 75P | 80P |
| | Charpy Notched Impact Strength** | ISO 7391 b.o. 179-1eA | -30°C, 3 mm | $kJ/m^2$ | 55C | 65C | 70C | 70C | 75C | 80P |
| | Izod Notched Impact Strength** | b.o. ISO 180-A | 23°C, 3.2 mm | $kJ/m^2$ | 65P | 75P | 80P(C) | 80P(C) | 85P(C) | 90P |
| | Izod Notched Impact Strength** | b.o. ISO 180-A | -30°C, 3.2 mm | $kJ/m^2$ | 12C | 14C | 14C | 14C | 14C | 16C(P) |
| C | Puncture Maximum Force | ISO 6603-2 | 23°C | N | 4900 | 5100 | 5400 | 5400 | 5400 | 5600 |
| C | Puncture Energy | ISO 6603-2 | 23°C | J | 55 | 55 | 60 | 60 | 60 | 60 |
| C | Puncture Maximum Force | ISO 6603-2 | -30°C | N | 5900 | 6000 | 6300 | 6300 | 6300 | 6500 |
| C | Puncture Energy | ISO 6603-2 | -30°C | J | 60 | 65 | 65 | 65 | 65 | 70 |
| | Ball Indentation Hardness | ISO 2039-1 | | $N/mm^2$ | 115 | 115 | 115 | 115 | 115 | 111 |
| **Thermal Properties** | | | | | | | | | | |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 1.80 MPa | °C | 124 | 125 | 124 | 124 | 125 | 129 |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 0.45 MPa | °C | 137 | 139 | 136 | 137 | 137 | 141 |
| | Vicat Softening Temperature | ISO 306 | 50 N; 120°C/h | °C | 146 | 146 | 145 | 145 | 146 | 150 |
| | Resistance to heat (ball pressure test) | IEC 60695-10-2 | | °C | 136 | 138 | 138 | 136 | 136 | 140 |
| C | Coefficient of Linear Thermal Expansion, Parallel | ISO 11359-1, -2 | 23 to 55°C | $10^{-4}$/K | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 |
| C | Coefficient of Linear Thermal Expansion, Transverse | ISO 11359-1, -2 | 23 to 55°C | $10^{-4}$/K | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 | 0.65 |
| **Other Properties** | | | | | | | | | | |
| C | Water Absorption (saturation value) | ISO 62 | Water at 23°C | % | 0.30 | 0.30 | 0.30 | 0.30 | 0.30 | 0.30 |
| C | Water Absorption (equilibrium value) | ISO 62 | 23°C; 50% r.h. | % | 0.12 | 0.12 | 0.12 | 0.12 | 0.12 | 0.12 |
| C | Density | ISO 1183-1 | | $kg/m^3$ | 1200 | 1200 | 1200 | 1200 | 1200 | 1200 |
| | Injection molding – melt temperature | ISO 294 | | °C | 280 | 280 | 290 | 290 | 300 | 300 |
| | Injection molding – mold temperature | ISO 294 | | °C | 80 | 80 | 80 | 80 | 80 | 80 |
| | Injection molding – injection velocity | ISO 294 | | mm/s | 200 | 200 | 200 | 200 | 200 | 200 |

**C -** These property characteristics are taken from the CAMPUS® plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

**Impact properties: N = non-break, P = partial break, C = complete break

# Bayblend® Typical Values

Bayblend®

| | | | | | Medical | | Limited Biocompatibility | | Standard |
|---|---|---|---|---|---|---|---|---|---|
| Properties | | Standard | Test Condition | Units | M850 XF | M750 | M301 FR | M303 FR | FR3010 |
| **Rheological Properties** | | | | | | | | | |
| C | Melt Volume Rate | ISO 1133 | 240°C/5 kg | $cm^3$/10min | | | 25 | | 15 |
| C | Melt Volume Rate | ISO 1133 | 260°C/5 kg | $cm^3$/10min | 25 | 11 | | 11 | |
| C | Molding Shrinkage, Parallel | ISO 294-4 | 60x60x2mm; 500 bar 150x105x3 mm; 260 °C/MT80 °C | % | 0.55-0.75 | 0.7-0.9 | 0.5-0.7* | 0.5-0.7 | 0.5-0.7* |
| C | Molding Shrinkage, Normal | ISO 294-4 | 60x60x2mm; 500 bar 150x105x3 mm; 260 °C/MT80 °C | % | 0.55-0.75 | 0.7-0.9 | 0.5-0.7* | 0.5-0.7 | 0.5-0.7* |
| **Mechanical Properties** | | | | | | | | | |
| C | Tensile Modulus | ISO 527-1, -2 | 1 mm/min | MPa | 2500 | 2000 | 2600 | 2650 | 2700 |
| C | Yield Stress | ISO 527-1, -2 | 50 mm/min | MPa | 62 | 47 | 60 | 69 | 60 |
| C | Yield Strain | ISO 527-1, -2 | 50 mm/min | % | 4.9 | 4.8 | 4.0 | 5.0 | 4.0 |
| C | Nominal Strain at break | ISO 527-1, -2 | 50 mm/min | % | >50 | >50 | >30 | >50 | >50 |
| | Izod Notched Impact Strength** | ISO 180-A | 23°C | $kJ/m^2$ | 48 | 45 | 40 | 40 | 35 |
| | Izod Notched Impact Strength** | ISO 180-A | -30°C | $kJ/m^2$ | 15C | 35P | | 10 | 10 |
| **Thermal Properties** | | | | | | | | | |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 1.80 MPa | °C | 109 | 104 | 85 | 98 | 90 |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 0.45 MPa | °C | 127 | 127 | 95 | 106 | 100 |
| | Vicat Softening Temperature | ISO 306 | 50 N; 120°C/h | °C | 131 | 126 | 105 | 115 | 110 |
| C | Coefflcient of Linear Thermal Expansion, Parallel | ISO 11359-1, -2 | 23 to 55°C | $10^{-4}$/K | 0.70 | 0.85 | 0.76 | 0.68 | 0.76 |
| C | Coefflcient of Linear Thermal Expansion, Transverse | ISO 11359-1, -2 | 23 to 55°C | $10^{-4}$/K | 0.70 | 0.85 | 0.80 | 0.72 | 0.80 |
| | Burning behavior UL 94 (1.5 mm) [UL recognition] | UL 94 | 1.5 mm | Class | - | - | V-0 | V-0 | V-0 |
| | Burning behavior UL 94 [UL recognition] | UL 94 | 2.0 mm | Class | - | - | 5VB | 5VB | 5VB |
| | Burning behavior UL 94 [UL recognition] | UL 94 | 3.0 mm | Class | - | - | 5VA | 5VA | 5VA |
| **Electrical Properties** | | | | | | | | | |
| | Relative permittivity | IEC 60250 | 100 Hz | | 2.9 | 3.0 | 3.2 | 3.2 | 3.2 |
| | Relative permittivity | IEC 60250 | 1 MHz | | 2.9 | 2.9 | 3.1 | 3.1 | 3.1 |
| | Dissipation Factor | IEC 60250 | 100 Hz | $10^{-4}$ | 30 | 25 | 50 | 37 | 50 |
| | Dissipation Factor | IEC 60250 | 1 MHz | $10^{-4}$ | 90 | 105 | 70 | 75 | 70 |
| | Volume resistivity | IEC 60093 | | Ohm·m | 1 E14 | 1 E14 | 1 E14 | 1 E15 | 1E14 |
| | Surface resistivity | IEC 60093 | | Ohm | 1 E17 | 1 E16 | 1 E16 | 1 E17 | 1E16 |
| | Electrical strength | IEC 60243-1 | 1 mm | kV/mm | 35 | 35 | 30 | 35 | 35 |
| **Other Properties** | | | | | | | | | |
| C | Water Absorption (saturation value) | ISO 62 | Water at 23°C | % | 0.7 | 0.6 | 0.5 | 0.5 | 0.5 |
| C | Water Absorption (equilibrium value) | ISO 62 | 23°C; 50% r.h. | % | 0.2 | 0.2 | 0.2 | | 0.2 |
| C | Density | ISO 1183-1 | | $kg/m^3$ | 1140 | 1120 | 1190 | 1190 | 1180 |
| | Injection molding – melt temperature | ISO 294 | | °C | 260 | 260 | 240-270 | | 240 |
| | Injection molding – mold temperature | ISO 294 | | °C | 80 | 80 | 60-80 | | 80 |
| | Injection molding – injection velocity | ISO 294 | | mm/s | 240 | | 240 | | 240 |

**C -** These property characteristics are taken from the CAMPUS® plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

* Measured at 240 °C

**Impact properties: N = non-break, P = partial break, C = complete break

# Apec® Typical Values

Apec®

| | | | | | Medical |
|---|---|---|---|---|---|
| **Properties** | | **Standard** | **Test Condition** | **Units** | **Apec® 1745** |
| **Rheological Properties** | | | | | |
| C | Melt Volume Rate | ISO 1133 | 330°C/2.16 kg | $cm^3$/10min | 17 |
| C | Molding Shrinkage, Parallel | ISO 294-4 | Value range based on general and practical experience 60x60x2mm (600 bar) | % | 0.8 |
| C | Molding Shrinkage, Normal | ISO 294-4 | Value range based on general and practical experience 60x60x2mm (600 bar) | % | 0.8 |
| **Mechanical Properties** | | | | | |
| C | Tensile Modulus | ISO 527-1, -2 | 1 mm/min | MPa | 2400 |
| C | Yield Stress | ISO 527-1, -2 | 50 mm/min | MPa | 70 |
| C | Yield Strain | ISO 527-1, -2 | 50 mm/min | % | 6.8 |
| C | Nominal Strain at break | ISO 527-1, -2 | 50 mm/min | % | >50 |
| C | Charpy Impact Strength** | ISO 179-eU | 23°C | $kJ/m^2$ | N |
| C | Charpy Impact Strength** | ISO 179-eU | -30°C | $kJ/m^2$ | N |
| | Flexural Modulus | ISO 178 | 2 mm/min | MPa | 2400 |
| | Flexural Strength | ISO 178 | 2 mm/min | MPa | 105 |
| **Thermal Properties** | | | | | |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 1.80 MPa | °C | 148 |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 0.45 MPa | °C | 160 |
| | Vicat Softening Temperature | ISO 306 | 50 N; 120°C/h | °C | 170 |
| C | Coefficient of Linear Thermal Expansion, Parallel | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.65 |
| C | Coefficient of Linear Thermal Expansion, Transverse | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.65 |
| | Relative Temperature Index (Tensile strength) | UL 746B | | °C | 140 |
| | Relative Temperature Index (Tensile impact strength) | UL 746B | | °C | 130 |
| | Relative Temperature Index (Electric strength) | UL 746B | | °C | 140 |
| | Burning behavior UL 94 (1.5 mm) UL recognition | UL 94 | 1.5 mm | Class | HB |
| | Burning behavior UL 94 (1.5 mm) UL recognition | IEC 60695-11-10, -20 | 1.5 mm | Class | HB |
| | Oxygen Index | ISO 4589-2 | Method A | % | 25 |
| **Electrical Properties** | | | | | |
| | Relative permittivity | IEC 60250 | 100 Hz | | 3.0 |
| | Relative permittivity | IEC 60250 | 1 MHz | | 2.9 |
| | Dissipation Factor | IEC 60250 | 100 Hz | 10-4 | 10 |
| | Dissipation Factor | IEC 60250 | 1 MHz | 10-4 | 80 |
| | Volume resistivity | IEC 60093 | | Ohm·m | 1E15 |
| | Surface resistivity | IEC 60093 | | Ohm | 1E16 |
| | Comparative Tracking Index CTI | IEC 60112 | Solution A | Rating | 250 |
| **Other Properties** | | | | | |
| C | Water Absorption (saturation value) | ISO 62 | Water at 23°C | % | 0.3 |
| C | Water Absorption (equilibrium value) | ISO 62 | 23°C; 50% r.h. | % | 0.12 |
| C | Density | ISO 1183-1 | | $kg/m^3$ | 1170 |
| | Injection molding – melt temperature | | | °C | 330 |
| | Injection molding – mold temperature | | | °C | 100 |

**C -** These property characteristics are taken from the CAMPUS® plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

**Impact properties: N = non-break, P = partial break, C = complete break

# Makroblend® Typical Values

Makroblend®

| | | | | | Limited Biocompatibility | Standard | | | |
|---|---|---|---|---|---|---|---|---|---|
| Properties | | Standard | Test Condition | Units | M525 | EC150 | EL700 | EL703 | M4000 FR |
| **Rheological Properties** | | | | | | | | | |
| | Melt Volume Rate | ISO 1133 | 260°C/5 kg | $cm^3$/10min | 21 | | | | 20 |
| | Melt Volume Rate | ISO 1133 | 270°C/5 kg | $cm^3$/10min | | 31 | 15 | 26 | |
| C | Molding Shrinkage, Parallel | ISO 294-4 b.o. ISO 2577 | Value range based on general and practical experience (600 bar) | % | 0.7-0.9 | 0.6-0.8 | 0.6-0.8 | 0.6-0.8 | 0.8-1.0 |
| C | Molding Shrinkage, Normal | ISO 294-4 | Value range based on general and practical experience (600 bar) | % | 0.7-0.9 | 0.6-0.8 | 0.6-0.8 | 0.6-0.8 | 0.8-1.0 |
| **Mechanical Properties** | | | | | | | | | |
| C | Tensile Modulus | ISO 527-1, -2 | 1 mm/min | MPa | 2000 | 2500 | 2350 | 2300 | 2287 |
| C | Yield Stress | ISO 527-1, -2 | 50 mm/min | MPa | 55 | 59 | 58 | 56 | 57 |
| C | Yield Strain | ISO 527-1, -2 | 50 mm/min | % | 4.5 | 4.2 | 4.5 | 4.5 | 4.5 |
| C | Nominal Strain at break | ISO 527-1, -2 | 50 mm/min | % | >50 | 90 | 100 | 100 | >50 |
| | Izod Notched Impact Strength** | ISO 180-A | 23°C | $kJ/m^2$ | 60 | 50[1] | 60 | 50 | >30 |
| | Izod Notched Impact Strength** | ISO 180-A | -20°C | $kJ/m^2$ | 45 | 10[1] | 30 | 15 | >10 |
| **Thermal Properties** | | | | | | | | | |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 1.80 MPa | °C | 75 | 90 | 100 | 96 | 83 |
| C | Temperature of Deflection under Load | ISO 75-1, -2 | 0.45 MPa | °C | 100 | 105 | 123 | 119 | 105 |
| | Vicat Softening Temperature | ISO 306 | 50 N; 120°C/h | °C | 122 | 114 | 136 | 132 | 128 |
| C | Coefflcient of Linear Thermal Expansion, Parallel | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.9 | | 0.8 | 0.7 | 0.9 |
| C | Coefflcient of Linear Thermal Expansion, Transverse | ISO 11359-1, -2 | 23 to 55°C | 10-4/K | 0.9 | | 0.9 | 0.8 | 0.9 |
| | Burning behavior UL 94 (1.5 mm) [UL recog-nition] | UL 94 | 1.5 mm | Class | | V-0[2] | V-0 | V-0 | V-0 (2mm) |
| | Burning behavior UL 94 [UL recognition] | UL 94 | 3.0 mm | Class | | 5VA[3] | 5VA | 5VA | 5VA |
| **Electrical Properties** | | | | | | | | | |
| | Relative permittivity | IEC 60250 | 100 Hz | | 3.2 | | 3.1 | 3.5 | |
| | Relative permittivity | IEC 60250 | 1 MHz | | 3.1 | | 3.0 | 3.3 | |
| | Dissipation Factor | IEC 60250 | 100 Hz | 10-4 | 30 | | 20 | 30 | |
| | Dissipation Factor | IEC 60250 | 1 MHz | 10-4 | 150 | | 130 | 200 | |
| | Volume resistivity | IEC 60093 | | Ohm·m | > 1E14 | | 1E14 | 1E14 | |
| | Surface resistivity | IEC 60093 | | Ohm | > 1E15 | | 1E16 | 1E16 | |
| | Comparative Tracking Index CTI | IEC 60112 | Solution A | Rating | 225 | | 225 | 200 | |
| **Other Properties** | | | | | | | | | |
| C | Water Absorption (saturation value) | ISO 62 | Water at 23°C | % | | | 0.5 | 0.5 | |
| C | Water Absorption (equilibrium value) | ISO 62 | 23°C; 50% r.h. | % | | | 0.2 | 0.2 | |
| C | Density | ISO 1183-1 | | $kg/m^3$ | 1220 | 1220 | 1280 | 1300 | |
| | Injection molding – melt temperature | | | °C | 260 | 270 | 270 | 270 | 240-260 |
| | Injection molding – mold temperature | | | °C | 60 | 70 | 70 | 70 | 45-75 |

1. Measured at 3mm thickness; 2. V-0 at 0.75 mm; 3. 5VA at 2.3 mm;

**C** - These property characteristics are taken from the CAMPUS® plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

** Impact properties: N = non-break, P = partial break, C = complete break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