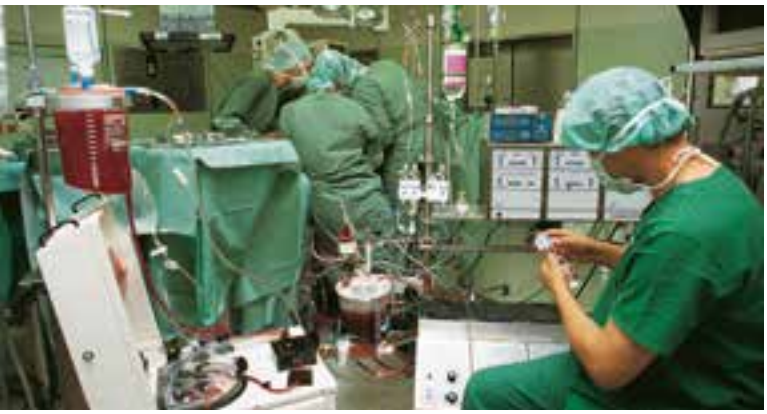
Makrolon®, Apec® and Bayblend® for medical devices

Makrolon®, Apec® and Bayblend® – ideal materials for medical equipment

Plastic – an ideal material for medical* and laboratory equipment

The first thing that springs to mind when people hear the words Bayer and medicine is Aspirin® or some other pharmaceutical product. Few people are aware of the fact that Bayer supplies manufacturers of medical products with a host of materials, such as thermoplastic materials and films, thereby making an important contribution towards further developments and discoveries in medical technology.



Our staff in the research and development departments are constantly working on new and improved tailor-made materials for this field of application. As you can see from the product overview below, Bayer's range does not include the plastics most widely used for medical purposes – polyethylene (PE), polystyrene (PS), polyvinyl chloride (PVC) and polypropylene (PP).

Instead, we offer a range of engineering plastics. These are used to solve problems whenever the property profile of a standard plastic is unable to meet the demands of medical products.

Engineering plastics from Bayer are encountered in every field of medical technology today: be it in diagnostics or surgery, in nursing or in the laboratory. The applications are equally diverse, ranging from films for sterile packs through animal breeding cages and asthma inhalers all the way to life-saving devices for supporting vital organs, such as artificial kidneys or oxygenators.

This brochure is intended to provide an overview of the range of Bayer engineering plastics and to offer guidelines for selecting suitable plastics for new developments in medical and laboratory equipment.

PLASTICS OVERVIEW
Table 1

Trade name**	Type of resin	Abbreviated designation
Makrolon®	Polycarbonate	PC
Makrofol®	Polycarbonate	PC films
Bayfol®	Polycarbonate Blend	PC Blend films
Apec®	Copolycarbonate	PC-HT
Bayblend®	Polycarbonate / acrylonitrile butadiene styrene copolymer blend	(PC+ABS)

** The product families listed here are only a selection from Bayer MaterialScience's plastics portfolio.

The condensed form in which the data are presented is obviously not sufficient to allow a definitive decision to be reached on the material grade to be used in each specific application. However, more detailed literature is available on each of the individual materials at www.plastics.bayer.com. We will be glad to advise you on the selection of suitable product grades and possibly put forward new material developments for your consideration.

* See warranty on page 26

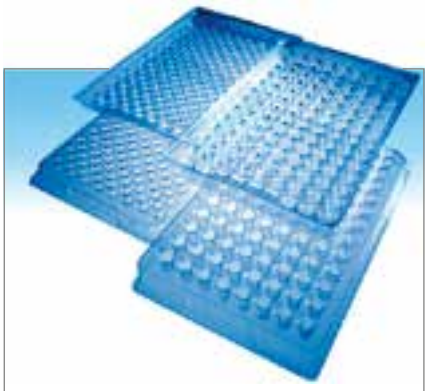
Makrofol® and Bayfol® – technical films for medical applications

The high-tech films with the trade names Makrofol® (polycarbonate films) and Bayfol® (polycarbonate blend films) have excellent optical, mechanical, thermal, and electrical properties.
Molded parts made of Makrofol® can be cleaned, disinfected, and sterilized using most of the methods employed in practice today. They are available in a range of thicknesses and surface textures and offer ideal characteristics for thermoforming, embossing and printing.

In addition to standard grades, there are also special grades in the form of light-scattering films, electrically conductive films and laser-markable grades.
Certain Makrofol® DE films meet certain biocompatibility test requirements of ISO Standard 10993-1 and USP class VI. They can be used for packaging implants and surgical instruments, for example. Further applications of Makrofol® and Bayfol® include front panels for various instruments (manufactured by in-mold decoration), backlit and warning displays, nameplates, decorative films and membrane switch overlays.
Makrofol® films are increasingly being used for the insurance cards issued by health funds because they meet the stringent demands on service life and resistance to mechanical and thermal stresses.

Components for Blood and fluid warmer made of Makrofol®

The Surgical Company's blood and fluid warmer "Fluido", produced by Medistad Medical B.V., is used in conjunction with innovative disposable cassettes partly made of Makrofol® DE 1-1, making it possible to heat blood using infrared technology.



Titration plates made of Makrofol®

Makrofol® DE 1-1 is the ideal material for highly transparent parts.
The material boasts high heat resistance and dimensional stability. It is exceptionally robust and can be shaped in three dimensions, e.g. by thermoforming.
Molded parts made of Makrofol® can be cleaned, disinfected, and sterilized using most of the methods employed in practice today. The smooth surface of the film is ideal for this purpose.

Makrolon® – for transparent and colored parts with high fracture resistance

The amorphous polycarbonate Makrolon® offers a unique combination of strength, hardness and rigidity with toughness and fracture resistance*. These properties are complemented by glass-like transparency, high heat resistance and good electrical insulating capacity.

The good processability, low shrinkage and low water absorption allow thin-section, lightweight parts to be produced with good dimensional stability.

A range of Makrolon® medical grades has been developed to meet the demands of medical technology. A heat deflection temperature of up to 135 °C permits sterilization with steam at 121 °C. Other suitable sterilization methods are with ethylene oxide gas and gamma radiation treatment. In the case of transparent, colorless parts made of standard Makrolon® medical grades, the latter process leads to a slight yellowish-green discoloration. Special grades with better color stability have therefore also been developed for gamma sterilization.

These include for example Makrolon® Rx1805, which has been developed especially for intravenous technology, is noted for its excellent lipid resistance, and is stabilized so that it can be sterilized using high-energy radiation.

Inhalers

Inhalers for the treatment of simple asthma and respiratory tract ailments must be compact, lightweight, simple to use and function reliably. Makrolon® succeeds exceptionally well in meeting the stringent requirements placed on specific functional components of the inhaler shown here, such as mechanical load-bearing properties and dimensional stability.

Hollow-fiber dialyzers

In cases of chronic kidney failure, substances usually eliminated with the urine are removed from the blood by ultrafiltration in a dialyzer or hemofilter. The transparent housings of these “artificial kidneys” are made of Makrolon®.

DALI® adsorber system

The housing of the DALI® adsorber system is made from the fracture-resistant polycarbonate Makrolon® 2458. This withstands pressurized hot-steam sterilization, where temperatures reach at least 121 °C for about 20 minutes.

* Further information at www.plastics.bayer.com

These special Makrolon® medical grades are biocompatible according to several test requirements of ISO 10993-1 (see table 3).

Thanks to its outstanding combination of properties, Makrolon® has also achieved considerable importance for medical products.

Examples include dialysis modules, oxygenators, cardiotomy reservoirs, blood heat exchangers, tube connectors, 3-way stopcocks, blood filters and injection systems.

Cardiotomy reservoir

The blood extracted from the thorax during surgery is collected in a cardiotomy reservoir, treated in a hematocrit and returned to the patient. Makrolon® was selected as a sturdy material for the housing, as its high transparency facilitates rapid visual inspection.

Centrifuge system

Many plastics have a tendency to yellowing during sterilization with gamma rays. Makrolon® RX2530 is stabilized against high-energy radiation. This is why the beaker-shaped bottom part, the lid and the circular carrier of the closed centrifuge system are made of this product.

Ampoules for needle-free injection system

With this needle-free injection system, the medication is not injected into the skin through a needle but is fired rapidly under the skin into the tissue at high pressure, almost without pain. The medication is filled into transparent ampoules of Makrolon® RX2530. Its strength and impact resistance ensure that the ampoules can withstand the high mechanical loads during the injection, especially the pressure of up to 300 bar.

Infusion systems

Infusion systems are in direct contact with blood and intravenously administered fluids. The components must therefore be biocompatible and sterilizable, and above all have high resistance to stress cracking against lipid-containing emulsions. Manifolds and three-way stopcocks made of lipid-resistant Makrolon® RX1805 can satisfy these requirements.

Micro forceps and scissors

Micro forceps and scissors for ophthalmic surgery are made by Alcon Grieshaber AG. In total, eight of the single-use operating instrument's individual components are made of Makrolon®.

Apec® – for steam sterilization up to 143 °C

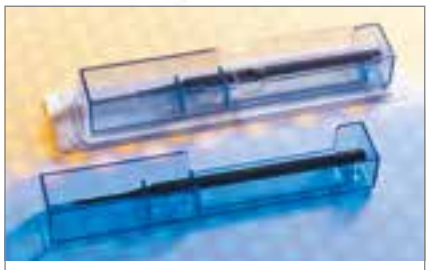
Apec® is the trade name for a range of amorphous copolycarbonates. The material is characterized by properties that are typical of Makrolon®, such as high transparency, toughness, light stability and strength, but with a higher heat resistance.

Apec® 1745 has a Vicat B softening temperature of 170 °C and allows higher temperatures for steam sterilization than standard polycarbonate (121 °C). Apec® can be steam sterilized at 134 °C and even at 143 °C, meaning that sterilization times and costs can be reduced. Other suitable sterilization methods are hot air at 160 °C, treatment with ethylene oxide, and gamma radiation.

Apec® 1745 meets test requirements of USP class VI and further biocompatibility tests according to ISO 10993-1 (see table 3). Apec® is currently used in the medical sector for components of dental lamp housings, components for surgical instruments, filters for safety valves, secretion containers and animal breeding cages.

Lamp housing for baby incubator

In this incubator, an infrared lamp keeps new-born babies warm. The lamp housing and the supporting arm are made of Apec®. The main arguments in its favor were its high heat resistance, toughness, stiffness and dimensional stability.



Operation boxes for scalpels in eye surgery

These operation boxes of Apec®, which are used to carry and store eye surgery scalpels, have to withstand two sterilization processes: first of all, the gamma rays after packaging in blister packs, and secondly the repeated hot-steam sterilization in the autoclave at 134 °C following operations.

Suction device

With this suction pump for emergency medicine, the receptacle on the side to catch the secretion from the wound is made of Apec® copolycarbonate, which means that it can simply be sterilized with steam at 134 °C after every use.

Respirator

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

Bayblend® – the ideal housing material with good flow properties

Bayblend® is the brand name for the product class of amorphous, thermoplastic polymer blends based on polycarbonate (PC) and acrylonitrile-butadiene-styrene copolymer (ABS) and the rubber-modified polycarbonate (PC) and styrene-acrylonitrile copolymer (SAN) blends.

Bayblend® M850 XF has been developed specifically for the medical sector. It is a non-reinforced PC+ABS blend with an ideal combination of heat resistance, stiffness and dimensional stability, plus excellent processing properties. In addition, Bayblend® M850 XF satisfies certain requirements laid down in ISO 10993-1 and is therefore highly suitable for a number of applications in the field of medical technology.

Bayblend® M850 XF is opaque and available either in its natural color or in a variety of custom shades.

The main area of application for Bayblend® M850 XF is in devices used in medical technology where particularly high heat resistance, impact strength and dimensional stability are specified.
Typical applications include housing components for drug dosage systems such as insulin pens and inhalation devices.

Product overview medical grades

Apec® 1745 is a transparent copolycarbonate suitable for repeated hot steam sterilization up to 143 °C. Easy release, high softening temperature, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Bayblend® M850 XF is an opaque, easy-flowing, non-reinforced PC+ABS blend. It is biocompatible according to many ISO 10993-1 test requirements. Global grade.

Makrolon® 2258 (MVR 36 cm^3 / 10 min) is a transparent, easy-flowing linear polycarbonate on the basis of bisphenol A. Easy release, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements.

Makrolon® 2458 (MVR 19 cm^3 / 10 min) is a transparent, easy-flowing linear polycarbonate on the basis of bisphenol A. Easy release, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Makrolon® 2558 (MVR 14.5 cm^3 / 10 min) is a transparent, medium-viscosity linear polycarbonate on the basis of bisphenol A. Easy release, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements.

Makrolon® 2658 (MVR 12.5 cm^3 / 10 min) is a transparent, medium-viscosity linear polycarbonate on the basis of bisphenol A. Easy release, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Makrolon® 2858 (MVR 9.5 cm^3 / 10 min) is a transparent, medium-viscosity linear polycarbonate on the basis of bisphenol A. Easy release, good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Makrolon® 3108 (MVR 6.0 cm^3 / 10 min) is a transparent, high-viscosity linear polycarbonate on the basis of bisphenol A. Good hydrolysis resistance, biocompatible according to many ISO 10993-1 test requirements.

Makrolon® Rx2430 (MVR 19 cm^3 / 10 min) is a transparent, easy-flowing polycarbonate on the basis of bisphenol A with a special additive system, biocompatible according to many ISO 10993-1 test requirements.

Makrolon® Rx2530 (MVR 14.5 cm^3 / 10 min) is a transparent, medium-viscosity polycarbonate on the basis of bisphenol A with a special additive system, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Makrolon® Rx1805 (MVR 6.0 cm^3 / 10 min) is a transparent, high-viscosity polycarbonate based on bisphenol A with a special additive system, biocompatible according to many ISO 10993-1 test requirements. Global grade.

Ampoules for needle-free injection system

Delivery form

Granules, packed in 25-kg PE bags, FIBC (flexible intermediate bulk containers – big bags), large cartons with a PE inliner or in bulk (silo). Apec® 1745 is available in 25-kg PE bags or large cartons with a PE inliner. All batches of Makrolon®, Bayblend® and Apec® are homogenized after production.

Makrolon® 2258 and Apec® 1745 are only available in transparent colors. Makrolon® 2458, 2558, 2658, 2858 and 3108 are supplied in various transparent and opaque colors.

Makrolon® Rx2430, Rx2530 and Rx1805 are supplied in a transparent violet color shade with the color code 451118. Bayblend® M850 XF is available in various opaque colors.

The production plants for Makrolon®, Bayblend® and Apec® have been certified according to DIN ISO by the appropriate quality organizations. The certificates can be found in the internet at http://www.bayermaterialscience.com. Registered customers can access the Safety Data Sheet on the Internet (bayerone.bayer.com). It can also be sent on request. The Safety Data Sheet includes data on labeling, transport and storage, as well as information on handling, product safety and toxicological and ecological profiles.

Physical and chemical properties

Thermal properties

Components made from Makrolon®, Bayblend® and Apec® are noted for their high heat resistance. At low loading levels (e.g. inherent weight) the parts do not undergo any significant deformation at up to

- ☐ 120 °C for Bayblend® M850 XF
- ☐ 135 °C for Makrolon®
- ☐ 160 °C for Apec® 1745.

Approximately 10 °C above this temperature molded parts start softening. Makrolon® assumes the molten state as from approximately 220 °C (Apec® 1745 at about 240 °C, Bayblend® M850 XF at about 200 °C). Even higher temperatures are required, however, before it attains a flowability that will permit it to be processed on injection molding machines and extruders. Lengthy periods of heating to temperatures in excess of 320 to 340 °C (Bayblend® M850 XF > 300 °C) lead to thermal decomposition, with carbon dioxide being split off, and discoloration.

The coefficient of linear thermal expansion is approx. $0.7 \cdot 10^{-4}$ / K (at 23–55 °C, according to ISO 11359-1,2).

If the material is subjected to temperatures in excess of about 80 °C for long periods of time, then a structural change will occur, as a function of the temperature and duration of the thermal treatment, which is characterized by a slight increase in the tensile and flexural strength and a reduction in the notched impact strength.

The maximum permitted service temperature for parts made of Makrolon®, Bayblend® and Apec® grades depends on the shape of the molded part, the type of loading and the speci-

fications. The temperature indices to IEC 60216-1 and UL 746 B can be regarded as practical reference values for the permitted maximum temperatures during long-term service. Where a component is subjected to a high temperature and mechanical loading simultaneously, the creep behavior must be taken into account. Further details on this can be found in the CAMPUS® database.

Optical and weathering properties

Makrolon® parts have a refractive index nD^{20} of 1.586. Apec® 1745 has a refractive index nD^{20} of 1.578. The virtually colorless, transparent grades possess a 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 in the course of time.

Molded parts made of medical grades of Makrolon®, Bayblend® and Apec® are not UV protected and are therefore not suitable for long-time outdoor exposure without a protective coating.

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

Behavior towards moisture and water (hydrolysis resistance)

Molded parts made of Apec® 1745, Bayblend® M850 XF or the Makrolon® grades mentioned in this brochure absorb only 0.10 % to 0.17 % water at room temperature with 50 % relative humidity. The physical / technological properties remain virtually unaffected. The dimensional changes are similarly insignificant. With immersion in water and rising temperatures, values of only 0.5 % or so are achieved. Molded parts made of Makrolon® may be cleaned many times with hot water in common household dishwashers, for example. The possible life time of a molded part depends on the material grade, the color, the processing conditions and the geometry of the part. However, although certain Makrolon® grades can be washed several thousands of times in hot water (for further information see our technical information sheet "Cleaning, disinfection and sterilization of Makrolon® articles" at www.plastics.bayer.com), permanent exposure to water at temperatures in excess of 60 °C is not to be recommended for Makrolon®, Bayblend® and Apec®, since hot water causes gradual chemical degradation, which may affect the optical and mechanical properties of the part. The same also applies to steam sterilization. The impact strength, notched impact strength and tensile strain at break are reduced through lengthy contact with hot water. This effect can also occur with storage in hot, very moist air.

Chemical resistance

Makrolon®, Bayblend® and Apec® are resistant to mineral acids, including in high concentrations, to a large number of organic acids (e.g. carbonic acid, lactic acid, oleic acid and citric acid), to oxidation 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® and Apec® are destroyed by alkaline solutions, ammonia gas and its solution, and amines. Makrolon®, Bayblend® and

Manifolds made of Makrolon® RX1805

Apec® dissolve in a large number of industrial solvents. Other organic compounds, such as benzene or acetone, cause it to swell. Many chemical substances may cause stress cracking. The resistance also depends on the internal and external level of stress to which the Makrolon®, Bayblend® and Apec® part is exposed (see "Stress crack test – Makrolon® moldings" under www.plastics.bayer.com). In the case of Makrolon®, the higher-viscosity grades generally have better chemical resistance.

Processing

Drying of the resin*

Makrolon®, Bayblend® and Apec® must be dried prior to processing. For injection molding, no more than 0.02 % residual moisture may be present in the granules, and for extrusion, no more than 0.01 %. Moisture in the melt leads to surface defects as well as to an increased reduction in molecular weight which can impair the properties of the part. Makrolon®, Bayblend® and Apec® should be dried in suitable dryers. We recommend a drying temperature of 100 °C for Bayblend® M850 XF, 120 °C for Makrolon® and 130 °C for Apec® 1745. The drying time is largely a function of the nature and type of the drying unit and can total 2 to 12 hours, depending on the drying capacity. Drying times of 2 to 4 hours are sufficient in modern dry-air dryers. One means 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.

Injection molding*

Makrolon®, Bayblend® and Apec® can be processed on all modern injection molding machines. Shut-off nozzles are suitable for Makrolon® given sufficient, uniform heating. For the processing of Bayblend® M850 XF and Apec® 1745, open nozzles, with a relatively large cross-section for Apec®, have proved successful. If there is a slight leakage of melt, this can generally be prevented by retracting the screw somewhat (removing the pressure from the melt). Molding shrinkage is more or less identical in all directions and amounts to 0.5 to 0.7 % and 0.6 to 0.8 % respectively.

The melt temperatures generally employed during processing are between 280 and 320 °C in general for Makrolon®, between 260 and 280 °C for Bayblend® M850 XF and between 320 and 340 °C for Apec® 1745.

Material damage has to be expected with excessively high processing temperatures or excessively long residence times in the cylinder and hot runner. This can lead to a reduction in toughness and / or to surface defects in the form of streaks.

It should be possible for the molds to be heated intensively and uniformly, and the mold temperature should be at least 80–120 °C for Makrolon®, 70–100 °C for Bayblend® M850 XF and 110–130 °C for Apec® 1745 to ensure parts with a low inherent stress and a good surface. It will not generally be necessary to employ mold release agents for the grades mentioned in this brochure.

Three-way stopcocks and luer lock connectors made of Makrolon® RX1805

* Further information at www.plastics.bayer.com

Under the recommended processing conditions, small quantities of decomposition product may be given off during processing. To preclude any risk to the health and well-being of the machine operatives, tolerance limits for the work environment must be ensured by the provision of efficient exhaust ventilation and fresh air 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.

Extrusion

Makrolon® 2258, 2458, 2558, 2658, 2858, Rx2430 and Rx2530, Bayblend® M850 XF and Apec® 1745 grades can be processed on extruders in exceptional cases. As a general rule, the higher-viscosity grades Makrolon® 3108 and Rx1805 are easier to extrude into sheets, films and profiles because of their higher melt stiffness.

Detailed information on injection molding and extrusion is contained in our technical information sheets at www.plastics.bayer.com.

Determination of internal stress level:
Stress crack test of Makrolon® moldings

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® and Apec® 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 on the external service stresses. Both compressive stresses and tensile stresses occur as a function of the geometry of the molded part. If excessive tensile stresses prevail, this can lead to local deformation zones in the surface and in the regions close to the surface (microcracks, crazes) and hence to weak points.

Certain chemicals also lead to crazing of Makrolon®, Bayblend® and Apec®. Parts with a high internal and external stress level are therefore less chemical resistant and also less resistant to moisture. It is possible to use test fluids for a rapid estimate of frozen-in stresses in Makrolon®, Bayblend® and Apec® moldings. After the molding has been immersed in the fluid, visible cracks form at points where specific stress values have been exceeded.
The test fluids have different “reaction thresholds” when it comes to their effect on the molding being tested. A detailed description is given in our technical information sheet “Stress crack test – Makrolon® moldings” at www.plastics.bayer.com.

Hardshell Cardiotomy Reservoire and Oxygenator in use

Post-treatment of molded parts

The following processing methods can be employed:

- Forming:
  thermoforming, e.g. bending, embossing; cold forming, e.g. high-pressure forming, folding
- Machining:
  sawing, drilling, milling, turning, planing, filing, thread cutting, punching, cutting
- Joining:
  screwing, adhesive bonding, welding
- Post-treatment:
  painting, printing, high vacuum metallization, laser inscription

Injection moldings made of Makrolon®, Bayblend® and Apec® can be machined without any difficulty. There is only a low tendency towards “smearing” on account of the high softening temperature. Only air or clean water can be employed as cooling agents. Makrolon®, Bayblend® and Apec® 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® and Apec® components can be vacuum metallized.

If parts made of Makrolon®, Bayblend® and Apec® are to be glued together (see at www.plastics.bayer.com), solvents such as methylene chloride (dichloromethane), 1,2-dichloroethane and 1,3-dioxolane are particularly suitable. These can be used to partially dissolve the contact surfaces prior to gluing (see safety advice for each solvent).

Two-pack 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® and Apec®.

Makrolon® or Bayblend® parts can be welded by means of vibration, friction, heated tool or hot gas welding. Ultrasonic welding and riveting are the preferred processes.

Cleaning, disinfection and sterilization methods for Makrolon®, Bayblend® and Apec® moldings

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, which manifests itself in the form of stress cracking. A detailed description of cleaning and disinfection is given in our technical information sheet "Cleaning, disinfection and sterilization of Makrolon® articles" at www.plastics.bayer.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, chemical additives / impurities and other factors. Therefore, the manufacturer of the medical device must check the suitability in each individual case.

Table 2

Sterilization method	Makrolon® 2258, 2458, 2558, 2658, 2858, 3108	Makrolon® Rx2430, Rx2530, Rx1805	Makrofol®	Apec® 1745	Bayblend® M850 XF
Ethylene oxide	Yes	Yes	Yes	Yes	Yes
Steam 121 °C	Yes	Yes	Yes	Yes	No
Steam 134 °C	No	No	No	Yes	No
Steam 143 °C	No	No	No	Yes	No
Hot air	Yes	Yes	Yes	Yes	No
Gamma rays	(Yes)[1]	Yes	(Yes)[1]	(Yes)[1]	Not tested
Electron beam	(Yes)[1]	Yes	(Yes)[1]	(Yes)[1]	Not tested

[1] See remarks in the chapter "Sterilization with high-energy radiation"

Sterilization by steam (saturated steam)

The sterilization temperature should not exceed 125 °C for Makrolon®, otherwise the molded parts will 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. This also generally applies if the material exhibits crazing and the molded part appears slightly milky after repeated sterilization with the high stresses that this imposes on the material. However, 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)

Makrolon® and Apec® have a high resistance to the effects of high-energy radiation. Their resistance is a function of the ambient conditions as well as of the applied radiation dose. 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 progressively yellower with each sterilization cycle. The special grades Makrolon® Rx2430, Rx2530 and Rx1805 are equipped with a special stabilizer against high-energy radiation. The color of these grades therefore changes less than that of standard grades when exposed to high-energy radiation. We do not yet have any experience regarding the behavior of Bayblend® M850 XF under high-energy radiation.

Biocompatibility – a “must” for many applications

Regulations (directives, standards, pharmacopoeia, European Standards)

Medical products in Europe must comply with the requirements of the following EU Directives, which are expressed in general terms:

- 90 / 385 / EEC (active implantable medical devices) and
- 93 / 42 / EEC with supplements and revisions (all other medical devices)

These have been taken over by the EU member countries as national laws or regulations. The Directives themselves do not stipulate the test methods or tolerance limits necessary for compliance with these requirements, but simply refer to EN standards (CEN and CENELEC), in which such methods and limits are prescribed. Medical products are only allowed onto the single European market if they bear the CE mark. This mark may be used if the manufacturer has carried out a conformity evaluation procedure under the auspices of a notified body.

International standards covering the biocompatibility of medical devices are being increasingly harmonized. The health authorities in the United States, Canada and the United Kingdom signed a joint commitment to the “Tripartite Biocompatibility Guidance for Medical Devices”, which is based on the test requirements of the US Pharmacopoeia, Class VI. On July 1, 1995, this was superseded by the similarly structured international standards ISO 10993 and EN 30993, the latter being a translation of ISO 10993 into the relevant European languages.

These two standards describe the program setting out physical, chemical and toxicological tests (graded according to the intensity of interaction between the medical product and the organism from short-term skin contact to long-term implant).
A summary of results obtained in certain tests according to ISO 10993-1 and the USP class VI is given in Tables 3 and 4. In the case of colored grades, it is advisable to check with us first.

Typical results of physico-chemical* and biocompatibility tests on medical grades
Table 3

	Test	USP Limits[2]	Makrolon®[1]	Apec®	Bayblend®
US Pharmacopoeia Class VI	Non-volatile	15 mg	< 1 mg	< 1 mg	< 1 mg
	Residue on ignition	5 mg	< 1 mg	< 1 mg	< 1 mg
	Heavy metals	1 ppm	< 1 ppm	< 1 ppm	< 1 ppm
	Buffering capacity	10 ml	< 1 ml	< 1 ml	< 1 ml
International Standard ISO 10993-1	**Acute systemic toxicity (in vivo) 72-hour observation**				
	Saline extract		No toxic response	No toxic response	No toxic response
	Ethanol in saline (1:20) extract		No toxic response	No toxic response	No toxic response
	Polyethylene glycol 400 extract		No toxic response	No toxic response	No toxic response
	Cottonseed oil extract		No toxic response	No toxic response	No toxic response
	Intracutaneous reactivity (in vivo) 72-hour observation				
	Saline extract		Non-reactive	Non-reactive	Non-reactive
	Ethanol in saline (1:20) extract		Non-reactive	Non-reactive	Non-reactive
	Polyethylene glycol 400 extract		Non-reactive	Non-reactive	Non-reactive
	Cottonseed oil extract		Non-reactive	Non-reactive	Non-reactive
	Muscle implantation (in vivo)				
	7 or 14 days' exposure		No significant effect	No significant effect	No significant effect
	Blood compatibility (in vitro): hemolysis				
	Direct and indirect (extract) contact		Non-hemolytic	Non-hemolytic	Non-hemolytic
	Cytotoxicity				
	48-hour exposure		Non-cytotoxic	Non-cytotoxic	Non-cytotoxic
	Pyrogenicity		Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
	Skin sensitization				
	Oil extract		Not sensitizing	Not sensitizing	Not sensitizing
	Saline extract		Not sensitizing	Not sensitizing	Not sensitizing
	Mutagenicity: Ames Test				
	Saline extract		Non-mutagenic	Non-mutagenic	Non-mutagenic
	95 % ethanol extract		Non-mutagenic	Non-mutagenic	Non-mutagenic

* These test results are typical measurements, but are not meant as a specification or binding

[1] before and after gamma sterilization using an average dose of 50 kGy

[2] only USP Class VI

Table 4

	Deionized water 1 h @ 121 °C, extract (ppm)	Saline solution (ppm) 1 hr @ 121 °C	Ash (ppm)
Barium	< 0.5	< 0.5	< 5.0
Cadmium	< 0.05	< 0.05	< 0.5
Lead	< 0.5	< 0.5	< 5.0

Typical results of heavy metal analysis of Makrolon®, Apec® and Bayblend® medical grades

Results of biocompatibility tests performed with BMS materials

A series of BMS products (medical grades) have been tested for biocompatibility following ISO 10993-1 and USP Class VI. The selected grades have met the requirements of the following tests (skin contact / up to 24 hours contact with circulating blood, tissue, bone, and dentin / up to 30 days contact with mucosal membranes, compromised surfaces, and bloodpath, indirect):

- ☐ Acute systemic toxicity
- ☐ Intracutaneous reactivity
- ☐ Muscle implantation
- ☐ Cytotoxicity
- ☐ Hemolysis – direct and extraction
- ☐ Physico-chemical tests
- ☐ Heavy metal analysis – atomic absorption (extraction and ash)
- ☐ Pyrogenicity study
- ☐ Sensitization – saline extract, oil extract
- ☐ Mutagenicity, Ames test – saline extract, 95 % ethanol extract

Written confirmation on met biocompatibility test requirements for a specific product can be sent on request.

Table 5

Polymer identity	Polycarbonate (PC)		Polycarbonate Blend (PC+ABS)	High-heat polycarbonate (PC-HT)
Trade name	Makrolon®		Bayblend®	Apec®
Type	2258 2458 2558 2658 2858 3108	Rx2430 Rx2530 Rx1805	M850 XF	1745
Compliance with regulations concerning biocompatibility[1]				
US Pharmacopoeia (USP) Class VI	Yes	Yes	Yes	Yes
ISO 10993-1[2]	Yes	Yes	Yes	Yes

1) Crystal clear Makrolon® and Apec® grades only, as well as for Bayblend® M850 XF. In case of colored grades it is advisable to check with us first.

2) - Skin contact
- Up to 24 hours contact with circulating blood, tissue, bone, and dentin
- Up to 30 days contact with mucosal membranes, compromised surfaces, and bloodpath, indirect

Biological tests, biocompatibility

The table below deals with the tests listed in EN ISO 10993-1: 2009 "Biological evaluation of medical devices – part 1: Evaluation and Testing" and the "Blue Book Memorandum G95-1" of the U.S. Food and Drug Administration (FDA).

Based on the above-mentioned regulations, the following biological risks should be taken into account for the various medical devices:

Table 6

Medical device categorization by			Biological effect											
Nature of body contact		Contact duration **A – Limited** (< 24 h) **B – prolonged** (24 h to 30 days) **C – permanent** (> 30 days)	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Subacute and subchronic toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic toxicity	Carcinogenicity	Reproductive/developmental toxicity	Biodegradation
Category	**Contact**													
Surface device	Skin	**A**	X	X	X									
		B	X	X	X									
		C	X	X	X									
	Mucosal membrane	**A**	X	X	X									
		B	X	X	X	0	0		0					
		C	X	X	X	0	X	X	0		0			
	Breached or compromised surface	**A**	X	X	X	0								
		B	X	X	X	0	0		0					
		C	X	X	X	0	X	X	0		0			
External communicating device	Bloodpath, indirect	**A**	X	X	X	X				X				
		B	X	X	X	X	0			X				
		C	X	X	0	X	X	X	0	X	X	X		
	Tissue/ bone/ dentin	**A**	X	X	X	0								
		B	X	X	X	X	X	X	X					
		C	X	X	X	X	X	X	X		X	X		
	Circulating blood	**A**	X	X	X	X		0		X				
		B	X	X	X	X	X	X	X	X				
		C	X	X	X	X	X	X	X	X	X	X		
Implant device	Tissue/ bone	**A**	X	X	X	0								
		B	X	X	X	X	X	X	X					
		C	X	X	X	X	X	X	X		X	X		
	Blood	**A**	X	X	X	X	X		X	X				
		B	X	X	X	X	X	X	X	X				
		C	X	X	X	X	X	X	X	X	X	X		

X: Tests per ISO 10993-1, O: Additional tests that may be applicable in the U.S.

Makrolon® typical values

Table 7

Grades for medical devices*												
Properties	**Test conditions**	**Units**	**Standards**	**2258**	**2458**	**2558**	**2658**	**2858**	**3108**	**Rx2430**	**Rx2530**	**Rx1805**
Rheological properties												
C Melt volume-flow rate (MVR)	300 °C; 1,2 kg	cm^3 / (10 min)	ISO 1133	36	19	14,5	12,5	9,5	6,0	19	14,5	6,0
C Molding shrinkage, parallel	60x60x2; 500 bar	%	ISO 294-4	0.65	0.65	0.65	0.65	0.65	0.7	0.6	0.6	0.7
C Molding shrinkage, normal	60x60x2; 500 bar	%	ISO 294-4	0.65	0.65	0.7	0.7	0.7	0.75	0.65	0.65	0.7
Mechanical properties (23 °C/50 % r. h.)												
C Tensile modulus	1 mm / min	MPa	ISO 527-1, -2	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400
C Yield stress	50 mm / min	MPa	ISO 527-1, -2	65	65	66	66	66	65	67	67	67
C Yield strain	50 mm / min	%	ISO 527-1, -2	6.0	6.0	6.1	6.1	6.1	6.3	6.1	6.1	6.3
C Nominal strain at break	50 mm / min	%	ISO 527-1, -2	> 50	> 50	> 50	> 50	> 50	> 50	> 50	> 50	> 50
C Tensile creep modulus	1 h	MPa	ISO 899-1	2,100	2,200	2,200	2,200	2,200	2,200		–	–
C Tensile creep modulus	1000 h	MPa	ISO 899-1	1,700	1,900	1,900	1,900	1,900	1,900		–	–
C Flexular modulus	2 mm / min	MPa	ISO 178	2,350	2,350	2,400	2,400	2,400	2,350	2,400	2,400	2,400
C Charpy impact strength	23 °C	kJ / m^2	ISO 179 / 1eU	N	N	N	N	N	N	N	N	N
C Charpy impact strength	–30 °C	kJ / m^2	ISO 179 / 1eU	N	N	N	N	N	N	N	N	N
C Charpy impact strength	–60 °C	kJ / m^2	ISO 179 / 1eU	N	N	N	N	N	N	N	N	N
Charpy notched impact strength	23 °C; 3 mm	kJ / m^2	acc. ISO 179 / 1eA	55P(C)	65P	70P	70P	75P	80P	70P	70P	80P
Charpy notched impact strength	–30 °C; 3 mm	kJ / m^2	acc. ISO 179 / 1eA	12C	14C	16C	16C	16C	18C(P)	14C	14C	16C
Izod notched impact strength	23 °C; 3,2 mm	kJ / m^2	acc. ISO 180 / A	65P(C)	75P(C)	80P(C)	80P(C)	85P	90P	80P(C)	80P(C)	90P
Izod notched impact strength	–30 °C; 3,2 mm	kJ / m^2	acc. ISO 180 / A	12C	12C	14C	14C	14C	16C(P)	12C	12C	14C
C Puncture maximum force	23 °C	N	ISO 6603-2	4,900	5,100	5,400	5,400	5,400	5,600	5,300	5,300	5,700
C Puncture maximum force	–30 °C	N	ISO 6603-2	5,900	6,000	6,300	6,300	6,300	6,500	6,200	6,200	6,600
C Puncture energy	23 °C	J	ISO 6603-2	55	55	60	60	60	60	60	60	65
C Puncture energy	–30 °C	J	ISO 6603-2	60	65	65	65	65	70	70	70	70
Thermal properties												
C Glass transition temperature	10 °C / min	°C	ISO 11357-1, -2	145	145	145	145	145	149		–	–
C Temperature of deflection under load	1,80 MPa	°C	ISO 75-1,-2	124	125	124	124	125	129	122	122	126
C Temperature of deflection under load	0,45 MPa	°C	ISO 75-1,-2	137	137	136	136	137	141	134	134	138
C Vicat softening temperature	50 N; 50 °C / h	°C	ISO 306	145	145	144	144	145	149	141	141	144
C Coefficient of linear thermal expansion, parallel	23 to 55 °C	10^{-4}/K	ISO 11359-1, -2	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
C Coefficient of linear thermal expansion, transverse	23 to 55 °C	10^{-4}/K	ISO 11359-1, -2	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Other properties (23 °C)												
C Water absorption (saturation value)	Water at 23 °C	%	ISO 62	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30
C Water absorption (equilibrium value)	23 °C; 50 % r.h.	%	ISO 62	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12
C Density	–	kg / m^3	ISO 1183	1,190	1,200	1,200	1,200	1,200	1,200	1,200	1,200	1,200
Material-specific properties												
Refractive index	Procedure A	–	ISO 489	1.586	1.586	1.586	1.586	1.586	1.587		–	–
	1 mm	%	ISO 13468-2	89	89	89	89	89	89		–	–
C Luminous transmittance (clear transparent materials)	2 mm	%	ISO 13468-2	89	89	89	89	89	89		–	–
	3 mm	%	ISO 13468-2	88	88	88	88	88	88		–	–
Processing conditions for test specimens												
C Injection molding-melt temperature	–	°C	ISO 294	280	280	290	290	300	300	280	280	300
C Injection molding-mold temperature	–	°C	ISO 294	80	80	80	80	80	80	80	80	80
C Injection molding-injection velocity	–	mm / s	ISO 294	200	200	200	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

* See warranty on page 26

Impact properties:
N = non break
P = partial break
C = complete break

Apec® typical values

Table 8

Grade for medical devices*				
Properties	**Test conditions**	**Units**	**Standards**	**1745**
Rheological properties				
C Melt volume-flow rate (MVR)	330 °C / 2.16 kg	cm^3 / (10 min)	ISO 1133	17
Melt mass-flow rate (MFR)	330 °C / 2.16 kg	g / (10 min)	ISO 1133	17
C Molding shrinkage, parallel		%	ISO 2577	0.8
C Molding shrinkage, normal		%	ISO 2577	0.8
Mechanical properties (23 °C / 50 % r. h.)				
C Tensile modulus	1 mm / min	MPa	ISO 527-1, -2	2,400
C Yield stress	50 mm / min	MPa	ISO 527-1, -2	70
C Yield strain	50 mm / min	%	ISO 527-1, -2	6.4
C Nominal tensile strain at break	50 mm / min	%	ISO 527-1, -2	> 50
C Charpy impact strength	23 °C	kJ/m^2	ISO 179-1eU	N
C Charpy impact strength	–30 °C	kJ/m^2		N
Charpy notched impact strength	23 °C; 3,0 mm	kJ/m^2	ISO 179-1eA	14
Charpy notched impact strength	–30 °C; 3,0 mm	kJ/m^2		12
C Puncture maximum force	23 °C; 2,0 mm	N	ISO6603-2	5,500
C Puncture maximum force	–30 °C; 2,0 mm	N		6,400
C Puncture energy	23 °C; 2,0 mm	J	ISO6603-2	60
C Puncture energy	–30 °C; 2,0 mm	J		65
Flexular modulus	2 mm / min	MPa	ISO 178	2,400
Flexular strength	5 mm / min	MPa	ISO 178	105
Ball indentation hardness	–	N/mm^2	ISO 2039-1	120
Thermal properties				
C Temperature of deflection under load, Af	1,80 MPa	°C	ISO 75-1, -2	146
C Temperature of deflection under load, Bf	0,45 MPa	°C	ISO 75-1, -2	160
Vicat softening temperature	50 N; 120 K / h	°C	ISO 306	170
Resistance to heat (ball pressure test)	–	°C	IEC60335-1	160
Relative temperature index (tensile strength)	1,5 mm; 3.0 mm	°C	UL 746B	140[1)]
Relative temperature index (tensile impact strength)	1,5 mm; 3.0 mm	°C	UL 746B	130[1)]
Relative temperature index (electric strength)	1,5 mm; 3.0 mm	°C	UL 746B	140[1)]
C Coefficient of linear thermal expansion, parallel	23 to 55 °C	10–4/K	ASTM E 831	0.7
C Coefficient of linear thermal expansion, transverse	23 to 55 °C	10–4/K	ASTM E 831	0.7
Other properties (23 °C)				
C Water absorption (saturation value)	water at 23 °C	%	ISO 62	0.3
C Humidity absorption (equilibrium value)	23 °C; 50 % r. h.	%	ISO 62	0.12
C Density	–	kg/m^3	ISO 1183	1,170
Material-specific properties				
Refractive index	–	–	ISO 489-A	1.578
C Luminous transmittance (clear transparent materials)	1 mm	%	DIN 5036-1	90
Processing conditions for test specimens				
C Injection molding-melt temperature	–	°C	ISO 294	330
C Injection molding-mold temperature	–	°C	ISO 294	100
C Injection molding-injection velocity	–	mm / s	ISO 294	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

1) Own measurement

* See warranty on page 26

Impact properties:
N = non break
P = partial break
C = complete break

Bayblend® typical values

Table 9

Grade for medical devices*				
Properties	**Test conditions**	**Units**	**Standards**	**M850 XF**
Rheological properties				
C Melt volume-flow rate (MVR)	260 °C / 5 kg	cm^3 / 10 min	ISO 1133	25
Molding shrinkage, parallel	150 x 105 x 3; 260 °C / WZ 80 °C	%	b.o. ISO 2577	0.55–0.75
Molding shrinkage, normal	150 x 105 x 3; 260 °C / WZ 80 °C	%	b.o. ISO 2577	0.55–0.75
Melt viscosity	1000 s^{-1}; 260 °C	Pa s	b.o. ISO 11443-A	210
Mechanical properties (23 °C / 50 % r. h.)				
C Tensile modulus	1 mm / min	MPa	ISO 527-1, -2	2,500
C Yield stress	50 mm / min	MPa	ISO 527-1, -2	62
C Yield strain	50 mm / min	%	ISO 527-1, -2	4.9
Stress at break	50 mm / min	MPa	ISO 527-1, -2	53
Strain at break	50 mm / min	%	b.o. ISO 527-1, -2	> 50
Izod impact strength	23 °C	kJ / m^2	ISO 180-U	N
Izod notched impact strength	23 °C	kJ / m^2	ISO 180-A	48
Izod notched impact strength	–30 °C	kJ / m^2	ISO 180-A	15
Thermal properties				
C Temperature of deflection under load	1,80 MPa	°C	ISO 75-1,-2	109
C Temperature of deflection under load	0,45 MPa	°C	ISO 75-1,-2	127
C Vicat softening temperature	50 N, 50 °C/h	°C	ISO 306	129
Vicat softening temperature	50 N, 120 °C/h	°C	ISO 306	131
C Coefficient of linear thermal expansion, parallel	23 bis 55 °C	10^{-4} / K	ISO 11359-1,-2	0.7
C Coefficient of linear thermal expansion, transverse	23 bis 55 °C	10^{-4} / K	ISO 11359-1,-2	0.7
C Burning behavior UL 94	0,85 mm	Class	UL 94	HB (Bayer Test)
Electrical properties (23 °C/50 % r. h.)				
C Relative permittivity	100 Hz	–	IEC 60250	2.9
C Relative permittivity	1 MHz	–	IEC 60250	2.9
C Dissipation factor	100 Hz	10^{-4}	IEC 60250	30
C Dissipation factor	1 MHz	10^{-4}	IEC 60250	90
C Volume resistivity	–	Ohm m	IEC 60093	1E14
C Surface resistivity	–	Ohm	IEC 60093	1E17
C Electrical strength	1 mm	kV/mm	IEC 60243-1	35
C Comparative tracking index CTI	Solution A	Rating	IEC 60112	250
Other properties (23 °C)				
C Water absorption (saturation value)	Water at 23 °C	%	ISO 62	0.7
C Water absorption (equilibrium value)	23 °C; 50 % r. h.	%	ISO 62	0.2
C Density	–	kg / m^3	ISO 1183-1	1,140
Processing conditions for test specimens				
C Injection molding-melt temperature	–	°C	ISO 294	260
C Injection molding-mold temperature	–	°C	ISO 294	80
C Injection molding-injection velocity	–	mm / sec	ISO 294	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

b.o. = based on

* See warranty on page 26

Impact properties:
N = non break
P = partial break
C = complete break

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GUIDANCE ON USE OF BAYER MATERIALSCIENCE PRODUCTS IN A MEDICAL APPLICATION

1. Purpose
The purpose of this Guidance Document is to provide information regarding the use of Bayer MaterialScience ("BMS") products in a medical application.

2. Medical Application
As used in this Guidance Document, the term "Medical Application" means all applications of medical devices wherein the medical device is manufactured with a BMS 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). If the medical device has more than one part or component, the term "Medical Application" shall apply only to the part or component which 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) and is also manufactured with a BMS Product(s). Medical devices implanted in the human body as well as components of drug delivery devices which are intended to be in direct contact with the drug are also included.

3. BMS Products for a Medical Application
The BMS products covered by this Guidance Document are fully reacted polymeric materials, reactive raw materials, dispersions, solutions, and non-reactive raw materials sold by BMS (hereinafter **"BMS Products"**). As used in this Guidance Document, the term **"BMS Products"** does not include final end-use products (e.g., medical devices) that are made from BMS raw materials, reacted materials, dispersions, or solutions.
BMS designates certain fully reacted BMS polymeric materials (e.g. certain plastics, sheets, and films) as **"Medical Grade."**
Other BMS Products, such as reactive raw materials (e.g., diisocyanates and polyols), dispersions, solutions, and non-reactive raw materials (which typically are added to substrate) are not designated as "Medical Grade" and shall not be considered candidates for a Medical Application unless BMS explicitly agrees, in writing, to sell such products for a Medical Application. Nonetheless, any determination as to whether a BMS product is appropriate for use in a Medical Application must be made solely by the purchaser of the BMS product(s) without relying upon any representations by BMS. In any event, BMS makes no representations regarding the suitability of a BMS Product for a particular Medical Application or final end-use product, as further explained in Section 4 below. Moreover, with respect to reactive raw materials (e.g., diisocyanates and polyols), dispersions, solutions, and non-reactive raw materials, BMS can make no representations regarding compliance with ISO Standard 10993-1 or other biocompatibility standards as such products must be reacted, have the solvent removed or be added to a substrate to form a solid or suitable material for an application as an article and therefore cannot be tested by themselves, or it is not appropriate to test them independent of the substrate, for meeting ISO Standard 10993-1 or other biocompatibility standards. It is the sole responsibility of the manufacturer of the 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.

Medical Grade
BMS Products that are designated as "Medical Grade", e.g., plastics, sheets, and films, meet certain biocompatibility test requirements of ISO Standard 10993-1: "Biological Evaluation of Medical Devices" 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.
BMS Products designated as "Medical Grade" shall not be considered candidates for the following types of Medical Applications unless BMS explicitly agrees, in writing, to sell such products for such applications: (a) cosmetic, reconstructive, or reproductive implant applications; (b) any other bodily implant applications; (c) applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days; or (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 BMS 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 BMS 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.
The designation as "Medical Grade" does not mean that BMS or anyone else has determined that the product is suitable for use in any particular Medical Application. BMS makes no representations regarding the suitability of a BMS Product for a particular Medical Application or final end-use product. A determination that the BMS Product is suitable for use in a particular Medical Application or final end-use product can only be made by the purchaser of the BMS product who utilizes it in a Medical Application and conducts all necessary testing and evaluation to support such a determination.

4. Appropriate Use of BMS Products
BMS has not performed clinical medical studies concerning the use of BMS Products. Moreover, BMS 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 BMS Products in a Medical Application.
BMS makes no representations or warranty regarding (and accepts no responsibility for determining) either: (a) the suitability of a BMS Product for a particular Medical Application or final end-use product or (b) the adequacy of any warning relating to a BMS Product or particular Medical Application or final end-use product. The suitability of BMS Products 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 BMS 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, and
- 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 postmarket 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. BMS 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 BMS Product in a specific Medical Application.

5. Sterilization
The sterilization method and the number of sterilization cycles a medical device can withstand will vary depending upon type/grade of product, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the manufacturer of the end-use final product must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and limitations and must fulfill postmarket surveillance obligations.
During sterilization, through the use of steam autoclaving or boiling water techniques, polyurethane materials may hydrolyze to their corresponding

precursor diamines (for example, aromatic polyurethane based on diphenylmethane diisocyanate (MDI) may hydrolyze and produce methylene dianiline (MDA), and aromatic polyurethane based on toluene diisocyanate (TDI) may hydrolyze and produce toluene diamine (TDA)). This condition needs to be considered by the device manufacturer in defining sterilization conditions.

6. Test Data
BMS may agree to provide existing test data and other information about its Medical Grade BMS Products or to perform additional testing of BMS Products. In so doing, BMS does not assume any responsibility to determine the suitability of a BMS Product for a particular Medical Application or final end-use product or to provide adequate warnings; moreover, any agreement by BMS to provide such data and/or information does not relieve the manufacturer of its sole responsibility to properly evaluate its final end-use product under actual end-use requirements, nor does it relieve the manufacturer of any of its other responsibilities described in this Guidance Document.

7. Re-use of Medical Devices
BMS does not warrant or represent that medical devices made from a BMS Product (including a Medical Grade BMS Product) are suitable for multiple uses. If the medical device is reprocessed and/or labeled for multiple uses, it is the responsibility of the manufacturer and/or reprocessor to determine the appropriate number of permissible uses by evaluating the device under actual sterilization, cleaning, and end-use conditions and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill postmarket surveillance obligations.

8. FDA Master Files
If the FDA requires proprietary information about any BMS Product as part of the 510(k) clearance or premarket application (PMA) approval process for the manufacturer's end-use final product, BMS may establish a Drug or Device Master File and grant a right of reference to it, in order to allow the FDA to review such information without disclosing BMS' proprietary information to the manufacturer.

9. Special Considerations
Only virgin Medical Grade BMS Products have been tested according to certain 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.
Over time, polyurethane materials may hydrolyze to their corresponding precursor diamines (for example, aromatic polyurethane based on diphenylmethane diisocyanate (MDI) may hydrolyze and produce methylene dianiline (MDA), and aromatic polyurethane based on toluene diisocyanate (TDI) may hydrolyze and produce toluene diamine (TDA)). This condition needs to be considered in any end-use application.

10. Risk of Failure
There is a risk of failure and adverse consequences with all Medical Applications and medical devices, including devices implanted in the human body and devices that are in contact with body fluids or tissues. There is also a risk of failure and adverse consequences for the use of BMS products in connection with any Medical Application and medical device, including devices implanted in the human body.

11. Packaging and Labeling
The purchaser of BMS Products shall be solely responsible for, or shall procure that the manufacturer and/or reprocessor of the medical device shall be responsible for (a) the design, production, assembly, packaging and labeling of the medical device which incorporates a BMS Product and (b) assigning the purpose for which that BMS Product is to be used. For the avoidance of doubt, BMS is not the manufacturer of any of the medical devices for which the BMS Products shall be sold and shall, to the extent permitted by law, not be liable as such.

12. Disclaimer of Warranty and Prohibition on Conflicting Oral Representations
1) To the extent permitted by law, BMS MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY, IMPLIED WARRANTY OF MERCHANTABILITY, IMPLIED WARRANTY FOR A PARTICULAR PURPOSE, OR OTHER IMPLIED WARRANTY CONCERNING THE SUITABILITY OF ANY BMS PRODUCT FOR USE IN ANY SPECIFIC MEDICAL DEVICE OR OTHER PRODUCT OR FOR ANY MEDICAL APPLICATION; AND
2) To the extent permitted by law, BMS MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY, IMPLIED WARRANTY OF MERCHANTABILITY, IMPLIED WARRANTY FOR A PARTICULAR PURPOSE, OR OTHER IMPLIED WARRANTY CONCERNING THE SUITABILITY OF ANY MEDICAL DEVICE OR OTHER PRODUCT MADE, WHOLLY OR IN PART, FROM ANY BMS PRODUCT.

NO BMS REPRESENTATIVE HAS THE AUTHORITY TO MAKE ANY ORAL REPRESENTATION THAT CONFLICTS WITH ANY PORTION OF THIS GUIDANCE.

13. Responsibility to Forward This Guidance Document
If the purchaser of any Medical Grade BMS Product is not the manufacturer of the final end-use product, it is the responsibility of the purchaser to forward this Guidance Document to such manufacturer.

14. Questions
In case of questions, please contact:
Within NAFTA BMS-HSEQ-PSRA
email: bmsmedicalapplication@bayerbms.com, phone +1 412-777-2835

Outside NAFTA BMS-IO-HSEQ-PRA
email: productsafety@bayerbms.com, phone +49 214 30 81761

This information and our technical advice – whether verbal, in writing or by way of trials – are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. Our advice does not release you from the obligation to verify the information currently provided – especially that contained in our safety data and technical information sheets – and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice are beyond our control and, therefore, entirely your own responsibility. Our products are sold in accordance with the current version of our General Conditions of Sale and Delivery.
Unless specified to the contrary, the values given have been established on standardized test specimens at room temperature.
The figures should be regarded as guide values only and not as binding minimum values. Please note that, under certain conditions, the properties can be affected to a considerable extent by the design of the mold/die, the processing conditions and the coloring.

Safety advice
The information given in the relevant safety data sheets must be observed when handling the recommended adhesives and solvents. The safety data sheets are provided by the supplier in each case. Further up-to-date information on the individual solvents is also available on the Internet in the GESTIS materials data base (GESTIS = Gefahrstoffinformationssystem der gewerblichen Berufsgenossenschaften; Dangerous Goods Information System of the German Employers' Accident Insurance Associations) at this internet address:
http://www.hvbg.de/e/bia/gestis/stoffdb/index.html

Part identification for recycling

>PC<

Parts should be identified in accordance with DIN EN ISO 11469; the marking to be applied to parts in Makrolon®: >PC<

>PC-HT<

The marking to be applied to parts in Apec® 1745: >PC-HT<

>PC+ABS<

The marking to be applied to parts in Bayblend® M850 XF: >PC+ABS <

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