

TOPAS[®]
Cyclic Olefin Copolymer (COC)

MEDICAL



TOPAS
Advanced Polymers

Topas Advanced Polymers

Effective January 1, 2006, the global COC business has been sold from Ticona/Celanese to the Japanese companies Daicel and Polyplastics and transferred into a new entity with the name Topas Advanced Polymers. The new company is located in Frankfurt/Germany and Florence/USA and has about 100 people working in Research & Development, Marketing & Sales, Production and Administration.

The History of TOPAS COC started in the early 90s at corporate research of Hoechst AG. In a new develop-

ed process first Norbornene will be synthesized from Dicyclopentadiene and Ethylene. In a second copolymerisation step with Ethylene using Metallocene-Catalysts the final product Cyclic Olefin Copolymer is generated. The TOPAS COC production plant in Oberhausen/Germany went on stream in year 2000 with an annual capacity of 30,000 tons.

Topas Advanced Polymers is producing and marketing cyclic olefin copolymers under its trademarks TOPAS® COC and Crystal Dew® and a bi-cyclic olefin Norbornene.

* TOPAS® is a registered trademark of Topas Advanced Polymers GmbH in Germany, the U.S. and other countries.

Contents

| | | |
|-----------|--|----------|
| 1. | TOPAS Cyclic Olefin Copolymer (COC) | 4 |
| 2. | TOPAS Applications Primary Pharmaceutical Packaging New options for primary pharmaceutical packaging Barrier for long life Biocompatibility Diagnostic Articles Innovations in diagnostic applications Sterilizability | 5 |
| 3. | Physical Properties of TOPAS | 7 |

Medical Applications

Innovative Solutions with glass-like Advantages

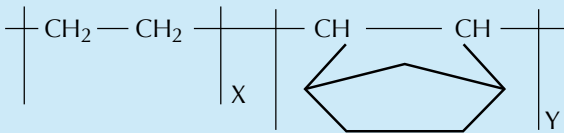
1. TOPAS Cyclic Olefin Copolymer (COC)

TOPAS is an amorphous, transparent copolymer based on the polymerization of ethylene and norbornene using metallocene catalysts.

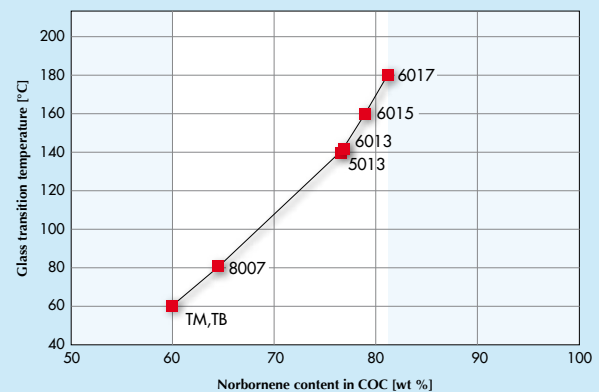
TOPAS possesses excellent properties for medical applications.

- ▶ **High transparency** ▶ High light transmission of 91%
- ▶ **High flowability and excellent replicability**
- ▶ **Excellent moisture and aroma barrier**
- ▶ **Excellent biocompatibility and inertness**
- ▶ **Variable glass transition temperatures from 65°C up to 178°C**
- ▶ **Chemical resistance, sterilizability**
- ▶ **Low specific gravity** ▶ Specific gravity of 1.02
- ▶ **High UV light transmittivity and low fluorescence**

TOPAS COC – A New Class of Amorphous Thermoplastics



Copolymer composition and heat resistance



Applications

▶ Primary Pharmaceutical Packaging

Pre-filled syringe

Vial / Bottle

PTP

▶ Diagnostic Articles

Microtiter plate

Bio chip

Cuvette

2 TOPAS Applications

Primary pharmaceutical packaging

New options for primary pharmaceutical packaging

The combination of high transparency, greater shatter resistance than glass and superior barrier to moisture makes TOPAS COC particularly attractive for prefillable primary pharmaceutical packaging. The material also has high purity and excellent biocompatibility.

Examples of applications are prefillable syringes and vials and a wide variety of prefillable containers which can be used, for example, as components of injection systems.

Injection molding and injection blow molding/injection stretch blow molding are typical manufacturing processes for this kind of pharma packaging.

Furthermore, TOPAS COC is used increasingly for pharmaceutical blister packaging because of its high transparency, biocompatibility and excellent moisture barrier.

Barrier for long life

The moisture barrier helps to extend the shelf life of pharmaceuticals and solutions stored in prefillable primary packaging. It keeps the moisture away from the contents or keeps the concentration of ready-prepared solutions constant.

With its remarkable property profile compared with known plastics, TOPAS COC offers new options for these applications.



Blister packaging film made with TOPAS

Biocompatibility

Primary pharmaceutical packaging is subject to regulations concerning the finished part. However, criteria for the use of plastics in these applications are specified in the national pharmacopoeias and by the responsible authorities.*

For this reason, a number of TOPAS grades have been studied in a biocompatibility test program. The TOPAS grades studied meet the requirements of US Pharmacopoeia XXIII Class VI and ISO 10993. Certificates are available on request.



Prefillable syringes Schott TopPac™, manufactured by Schott Glas

Extraction tests and chemical characterizations corresponding to the US, EU and Japanese pharmacopoeia protocols have been carried out successfully on certain TOPAS grades.

In addition, an FDA Drug Master File (Number 12132) and an FDA Device Master File (Number 1043) have been established.

The monomers used for the manufacturing of the above mentioned product are listed in the EU-Directive 2002/72/EC, and in the new edition of the German "Bedarfsgegenständeverordnung" of December 23rd, 1997. The FDA Regulation Number is 21 CFR 177.1520.

* It is not possible to obtain a general approval for plastics in medical applications. However, TOPAS Advanced Polymers supports manufacturers and users of such products through biocompatibility studies and the compilation of Drug Master Files/Device Master Files for the selected product grades. These FDA documents contain confidential information on the formulations and production process and the toxicological data. With the agreement of TOPAS Advanced Polymers, the FDA authorities may examine the documents for a particular customer.

Medical Applications

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Diagnostic articles

Innovations in diagnostic applications

TOPAS grades developed specifically for applications in diagnostics have excellent light transmission in the near UV region as well as high transparency in the visible region.

Excellent resistance to aqueous and polar organic media, good biocompatibility and the ability to reproduce fine structures, makes TOPAS the material of choice for innovative applications in the area of diagnostic articles.

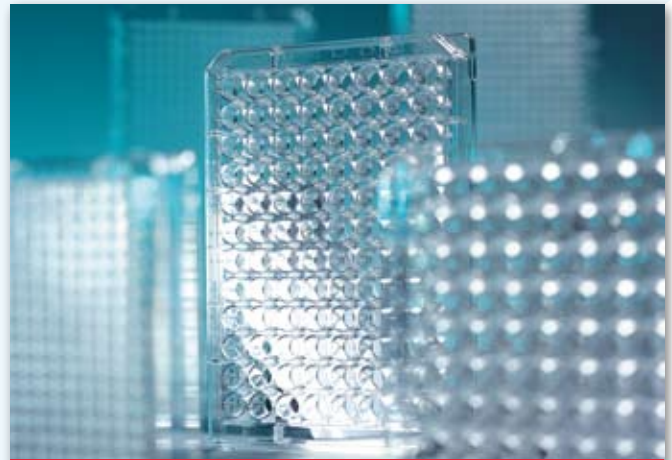
Examples of applications are microtiter plates for high throughput screening, microstructured cuvettes and test tubes for clinical analysis, and containers for spectroscopic monitoring of biochemical reactions.

Injection molding and injection blow molding/injection stretch blow molding are typical manufacturing processes for these diagnostic articles.

Sterilizability

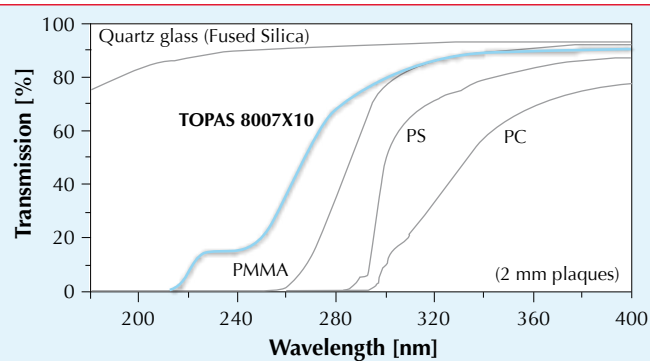
Plastics used in medicine and diagnostics often have to be sterilizable. TOPAS grades can withstand high-energy radiation (gamma rays and electron beams) and ethylene oxide.

The possibility of varying the glass transition temperature over a broad range gives access to materials whose softening point is sufficiently high to withstand steam sterilization. Where the article is sterilized more than once, ETO or gamma sterilization is recommended.



Microtiter plates manufactured from TOPAS

UV light transmission



Chemical resistance of TOPAS

| Medium | | Medium | |
|-----------------------|---|------------|---|
| Hydrochloric acid 36% | + | n-Pentane | - |
| Sulfuric acid 40% | + | Heptane | - |
| Sodium hydroxide 50% | + | Toluene | - |
| Dimethyl sulfoxide | + | Hexane | - |
| Acetonitrile | + | Benzene | - |
| Ethanol | + | Oleic acid | - |
| Isopropanol | + | | |

| TOPAS | Hot steam | | | ETO | High-energy radiation | |
|-------|-----------|--------|--------|-----|-----------------------|-----------|
| | 121 °C | 134 °C | 143 °C | | Gamma | Electrons |
| 8007 | - | - | - | + | + | + |
| 5013 | - | - | - | + | + | + |
| 6013 | + | - | - | + | + | + |
| 6015 | + | + | + | + | + | + |

3. Physical properties of TOPAS

| Property | Unit | Test method | 8007 | 6013 | 6015 | 5013 |
|--|---------------------------|------------------------------------|------------------------|------------------------|------------------------|------------------------|
| Melt volume rate MVR at 260 °C, 2.16 kg | ml/10 min | ISO 1133 | 32 | 14 | 4 | 48 |
| Melt volume rate MVR at HDT +115 °C, 2.16 kg | ml/10 min | ISO 1133 | 2 | 6 | 5 | 24 |
| Density | g/cm ³ | ISO 1183 | 1.02 | 1.02 | 1.02 | 1.02 |
| Water absorption (24 h immersion in water at 23 °C) | % | ISO 62 | < 0.01 | < 0.01 | < 0.01 | < 0.01 |
| Water vapor permeability at 23 °C and 85% relative humidity | g · mm/m ² · d | DIN 53 122 | 0.023 | 0.035 | 0.035 | 0.030 |
| Mold shrinkage (Shrinkage is dependent on processing conditions and part design) | % | – | 0.1 - 0.5 | 0.4 - 0.7 | 0.4 - 0.7 | 0.4 - 0.7 |
| Mechanical properties , measured under standard conditions, ISO 291 – 23/50 | | | | | | |
| Tensile strength [5 mm/min] | MPa | ISO 527, Part 1 and 2 | 63 | 63 | 60 | 46 |
| Elongation at break [5 mm/min] | % | ISO 527, Part 1 and 2 | 10*) | 2.7 | 2.5 | 1.7 |
| Tensile modulus [1 mm/min] | MPa | ISO 527, Part 1 and 2 | 2600 | 2900 | 3000 | 3200 |
| Impact strength (Charpy) | kJ/m ² | ISO 179/1eU | 20 | 15 | 15 | 13 |
| Notched impact strength (Charpy) | kJ/m ² | ISO 179/1eA | 2.6 | 1.8 | 1.6 | 1.6 |
| Ball indentation hardness, 30-sec-value | N/mm ² | ISO 2039 part 1, applied load 961N | 130 | 184 | 184 | 184 |
| Thermal properties | | | | | | |
| Heat deflection temperature HDT/B (0.45 MPa) | °C | ISO 75 , Part 1 and 2 | 75 | 130 | 150 | 130 |
| Coeffizient of linear thermal expansion | K ⁻¹ | ISO 11359, Part 1 and 2 | 0.7 · 10 ⁻⁴ | 0.6 · 10 ⁻⁴ | 0.6 · 10 ⁻⁴ | 0.6 · 10 ⁻⁴ |

*) Yield strain: 4.5%

Special TOPAS COC grades are available for use in medical and diagnostic applications. They conform to specifications for quality and uniformity that have been developed specifically for these sensitive appli-

cations. A special quality control program has been set up to secure purity and constancy of product properties.

Medical Applications

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IMPORTANT

The properties of molded articles can be affected by a variety of factors, including choice of molding material, additives, part design, molding conditions, and exposure to the environment. Customers should take responsibility as to the suitability of a particular material or part design, for a specific application. In addition, before commercializing a product that incorporates plastic parts, customers should take the responsibility of carrying out performance evaluations. Our company's products are not intended for use in medical and dental implants. Unless specified, the numerical values given in this literature are for reference purposes only and they do not indicate the necessary foundations for part design. Without fail, please follow the molding and other procedures explained in this literature. This literature does not guarantee specific properties for our company's products. Please take the responsibility of verifying industrial property rights of third parties.

NOTES TO USERS

- The property values given in this literature are measured values or representative values obtained from samples under various prescribed standards and test methods.
- This literature was compiled based on our company's accumulated experience and laboratory data, and the data shown here may not be applicable as is to parts used under different conditions. Accordingly, these contents do not guarantee that application is possible as is to your company's usage conditions. Regarding utilization, your company must make the final decisions.
- Your company should consider the technology rights and usage durability/potentiality concerning examples of practical use and application introduced in this literature. Furthermore, we do not assume our company's materials will be used in medical and dental implant applications and we do not recommend these applications.
- Regarding implementation of appropriate operations, please refer to the "Technical Catalogue" for the material suited to the particular objective.
- Please refer to the corresponding material safety data sheet (MSDS) for the material or grade employed regarding safe handling of our company's materials.
- The contents of this literature were compiled based on literature, information, and data available at that point in time. We reserve the right to revise without notice based on new knowledge.
- If there are any uncertainties regarding our company's products and explanatory literature, or the precautions referred to here, by all means please inquire to our company and consult with us.

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