TOPAS
Advanced Polymers




MEDICAL APPLICATONS WITH TOPAS® COC

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 contain-ers which can be used, for example, as compo-nents 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 prefill-able 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® COC

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® COC grades have been studied in a biocompatibility test program. The TOPAS® COC 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® COC 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.

Diagnostic articles

Innovations in diagnostic applications

TOPAS® COC 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® COC the material of choice for innovative applications in the area of diagnostic articles.

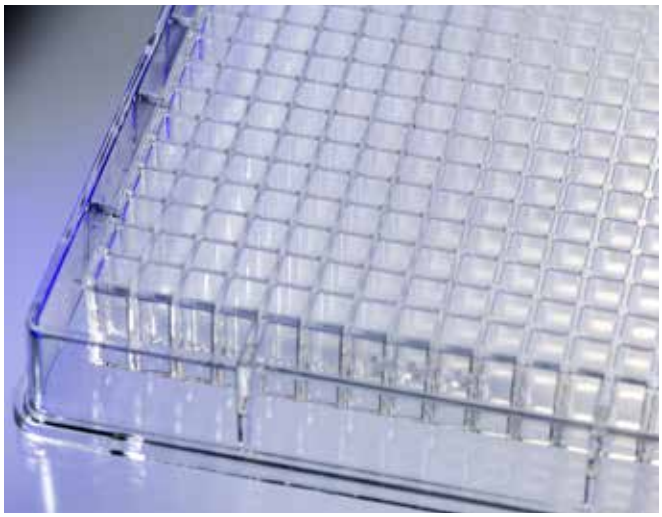
Examples of applications are microtiter plates for high throughput screening, microstructured cuvettes and test tubes for clinical analysis, and containers for spectroscopic monitoring of biochemical reactions.

Injection molding and injection blow molding/in-jection stretch blow molding are typical manufac-turing processes for these diagnostic articles.

Sterilizability

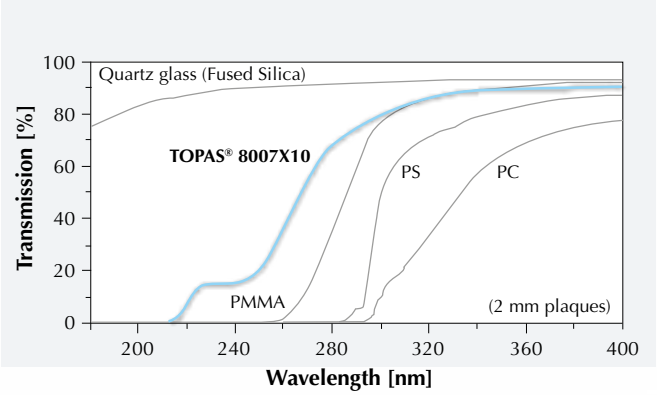
Plastics used in medicine and diagnostics often have to be sterilizable. TOPAS® COC grades can withstand high-energy radiation (gamma rays and electron beams) and ethylene oxide.

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® COC

UV light transmission



Chemical resistance of TOPAS® COC

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

Polyplastics
DAICEL Group

Physical properties of TOPAS® COC grades

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	$g \cdot mm/m^2 \cdot d$	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	$0.7 \cdot 10^{-4}$	$0.6 \cdot 10^{-4}$	$0.6 \cdot 10^{-4}$	$0.6 \cdot 10^{-4}$

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

TOPAS Advanced Polymers GmbH
Am Prime Parc 9
65479 Raunheim, Germany
Phone: +49 (0)1805 1 86727
eMail: info@topas.com
www.topas.com

Polyplastics USA, Inc.
27240 Haggerty Road, Suite E-20
Farmington Hills, MI 48331, USA
Phone: +1-248-479-8928
eMail: info@topas-us.com
www.topas.com

Polyplastics Co., Ltd.
JR Shinagawa East Building, 13F
18-1 Konan 2 - Chome, Minato-Ku
Tokyo, 108-8280, Japan
Phone: +81 03 6711 8610
www.polyplastics-global.com

TB003_2021.08_E