

资料表简讯 FAST FACT SHEET

工程材料 ENGINEERED MATERIALS | CALIBRE™ 2061 & 2060
聚碳酸酯树脂 Polycarbonate Resins



CALIBRE™ 2061 & 2060 聚碳酸酯树脂 Polycarbonate Resins

医疗耗材及设备因有机会与人体组织或体液接触，所以必须在使用前进行消毒，确保病人安全。为此，我们专门开发了 CALIBRE™ 聚碳酸酯 (PC) 树脂 2000 系列，以满足各种消毒程序和应用需求。

CALIBRE™ 2061 和 2060 聚碳酸酯 (PC) 系列，专门应用于蒸汽高压和环氧乙烷 (EtO) 消毒，树脂性能可见下表：

Both single- and multiple-use medical devices that come in contact with human tissue or bodily fluids must be sterilized for patient safety. The CALIBRE™ 2000 series from Trinseo has been specifically developed to handle a variety of sterilization processes and application requirements.

CALIBRE™ 2061 and 2060 Polycarbonate (PC) Resins are specially designed for medical applications involving steam autoclave and ethylene oxide (EtO) sterilization.

CALIBRE™ 2061 & 2060 PC 树脂消毒指引 Guidelines for the sterilization of CALIBRE™ 2061 & 2060 PC Resins

消毒技术 Sterilization Techniques	表现 (循环) Performance (Cycles)
蒸汽高压消毒 Steam autoclave	1-5
环氧乙烷 (EtO) 消毒 Ethylene Oxide (EtO)	

*盛禧奥位于德国施德塔、台湾新竹及北美地区的医疗级塑料制造及混炼设施，已通过 ISO 13485 最新的 2016 版本认证，风险管理和工艺验证更加严谨。Trinseo medical manufacturing and compounding facilities at Stade, Germany, Hsinchu, Taiwan, and in North America are ISO Certified and related global functions are ISO 13485 certified with the latest 2016 version that places a greater emphasis on risk management and process validation.



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ISO 13485:2016*

专为高压灭菌及环氧乙烷
消毒而设的医疗级树脂

Medical Polycarbonate Resins Designed
for Steam Autoclave & EtO Sterilization



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致力满足您的需求 Focused on meeting your needs

CALIBRE™ PC 树脂提供极佳的透明度、耐热和耐冲击性能；我们可以提供订制颜色。此外，此树脂备有数种熔融率选择。CALIBRE™ 2060 PC 树脂的特点是具有良好的抗环境应力开裂和韧性，详细可见下表：

CALIBRE™ PC Resins offer an excellent blend of clarity, heat resistance, high flow and impact resistance. Different melt flow rate options and custom colors are also available. CALIBRE™ 2060 PC Resins demonstrate good Environmental Stress Crack Resistance and toughness.

牌号 Grade	特性 Features	颜色 Colors	含脱模剂 Mold Release Agent	熔融率 Melt Flow Rate (g/10mins, ASTM D1238)	UL 94 等级 UL 94 Rating	生物相容性 Biocompatibility
CALIBRE™ 2061	• 耐热及耐冲击的平衡性能 Balanced feature of heat resistance and impact resistance	• 透明 Transparent • 不透明 Opaque • 提供订制颜色 Custom colors available	Yes	3-22	V2@1.5mm HB@3.0mm	ISO 10993
	• 高流动性 High flow			30	-	
CALIBRE™ 2060	• 良好的抗环境应力开裂 (ESCR) 性能 Good Environmental Stress Crack Resistance (ESCR) • 高韧性 High toughness • 耐低温冲击 Low-temperature impact		No	3	-	

提供订制颜色 Custom colors available

为满足行业需求，盛禧奥提供标准水白颜色 (色号: 030003)，亦提供一系列定制颜色，全部均同样符合 ISO 10993 标准。部份颜色选择包括红、黄、白、黑和灰。

Trinseo offers an array of custom colors to meet varying industry needs and specifications. All pre-color resins are made with the same properties and attributes of clear resins, and are fully compliant with ISO 10993. Some of our popular color options include red, yellow, white, black, and gray.

色号: Color codes:



透明 (水白)
Transparent (water white)
030003



红 Red



黄 Yellow



白 White



黑 Black



灰 Gray



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应用推介

Recommended applications

盛禧奥的 CALIBRE™ 2061 & 2060 PC 树脂广泛应用于注塑工艺，以下是一些应用推介：

Trinseo CALIBRE™ 2061 & 2060 PC Resins are commonly used for injection molding. Typical applications include:



法规支援及品质控制流程

Regulatory support and quality processes

我们理解医疗合规的重要性，盛禧奥已设立了完善的内部流程，确保行业严格的法规得以遵守。我们的法规专家服务全球；我们非常重视合规性，并努力保持领先地位。

盛禧奥以严格的质控指引、监控条件、及经过验证的各种流程来生产医疗等级树脂，并关注供应的稳定性。我们致力为客户提供一致、可信赖和可持续的产品。为了满足正规要求和文件需要，我们改善了管理流程，包括：

- 锁定配方
- 变更通知 (NOC)
- 批次追溯性
- 长期记录和样品保存期

我们的目标是给客户提供一个一站式的服务和支援。

We understand that medical regulatory compliance is critical for all manufacturers. Trinseo has developed internal processes to ensure the industry's stringent guidelines are met. As such, our regulatory expertise is recognized and appreciated globally, and we place a strong emphasis on maintaining this leadership position.

Trinseo produces its medical grade resins under stringent quality guidelines, controlled conditions and validated processes. Our multiple resin sources provide an assurance of supply. We are committed to providing product consistently, predictably and sustainably. To accommodate formal requirements and the need for documentation, we offer a Management of Change process that includes:

- Formulation Lock
- Notification of Change (NOC)
- Lot Traceability
- Extended Record and Sample Retention

Our goal is to provide end-to-end support to our customers.



盛禧奥 (Trinseo) 及其附属公司在文件印制方面秉承责任关怀® 和可持续发展的原则。为保护环境, 只印刷少量资料, 使用含可回收/再生纤维的纸张, 并尽可能采用 100% 豆制油墨印刷。

The principles of Responsible Care® and sustainability influence the production of printed literature for Trinseo S.A. and its affiliated companies. As a contribution towards the protection of our environments, Trinseo's printed literature is produced in small quantities and on paper containing recovered/post-consumer fiber and using 100 percent soy-based ink whenever possible.

产品监管 Product Stewardship

盛禧奥及其附属公司坚持一个基本原则, 即关怀所有制造、分销和使用其产品的人员, 以及我们生活的环境。我们的产品监管理念以此为基础, 我们根据该理念评估产品的安全性和对环境的影响, 并采取适当措施来保护我们的员工、公众健康和环境。我们成功的产品监管仰赖于与盛禧奥产品有关的每个人——从每件产品的最初构思和研究, 到制造、使用、销售、处置, 以及循环利用等所有环节。

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

客户须知 Customer Notice

基于保护人类健康和环境的原因, 客户有责任对其生产过程和对盛禧奥产品的应用进行全面监管和检查, 以确保盛禧奥产品不会以不当方式进行使用。盛禧奥人员将解答客户的问题, 并提供合理的技术支持。使用盛禧奥产品之前, 请务必查阅盛禧奥产品的相关资料, 包括安全数据表。最新安全数据表可从盛禧奥获取。

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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