



TRINSEO™

STYRON™ 2678 MED

聚苯乙烯树脂 Polystyrene Resins



ISO 13485:2016*

专为医疗应用而设的 生物相容聚苯乙烯树脂

Biocompatible Polystyrene Resins
for Medical Devices

盛禧奥的 STYRON™ 2678 MED 聚苯乙烯 (PS) 树脂适用于制作培养皿、移液管板以至包装应用。基于其高流动性及良好的刚性，并已通过 ISO 10993 测试，可用于特定的医疗应用上使用。技术细节详见下表：

Trinseo's STYRON™ 2678 MED Polystyrene (PS) Resins are a general-purpose polystyrene (GPPS) grade that can be used for multiple applications ranging from Petri dishes, to pipettes, to packaging. Featuring high flow and good rigidity, they have undergone ISO 10993 biocompatibility testing and are suitable for use in approved medical applications.

特性 Features	熔融率 Melt Mass-Flow Rate (g/10mins, ISO 1133)	拉伸强度 (屈服) Tensile Stress (Yield ISO 527-2/5)	弯曲模量 Flexural Modulus (ISO 178)	维卡软化温度 Vicat Softening Temperature (ISO 306/A120)	生物相容性及合规 Biocompatibility & Compliance
<ul style="list-style-type: none"> • 高流动 High flow • 良好的刚性 Good toughness • 极佳的透明度# Excellent transparency# • 优良的耐热性 Good heat resistance 	11 (200°C/5.0kg)	43 MPa	3500 MPa	93°C	<ul style="list-style-type: none"> • ISO 10993 • 符合美国(FDA) 及欧洲 食品接触法规 Complies with US (FDA) and European food contact regulation

#透光率约 90% Light transmission is approximately 90%

*盛禧奥的医疗制造设施及全球其他相关部门，均通过 ISO 13485 最新的 2016 版本认证，具更严谨的风险管理和工艺验证。Trinseo's medical manufacturing facilities 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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独特优势 Distinctive Advantages

STYRON™ 2678 MED PS 树脂是一种医用级聚合物，拥有高流动及良好的刚性。与其他医疗级树脂一样，STYRON™ 2678 MED PS 树脂亦提供配方锁定、延长变更通知和批次可追溯性。此树脂已通过 ISO 10993 测试，并符合美国和欧洲在食品接触方面的规定。

STYRON™ 2678 MED PS Resins are a medical-grade polymer with high flow and good toughness. Similar to other medical-grade resins, STYRON™ 2678 MED PS Resins also offer a formulation lock, extended notification of change, and lot traceability. The product complies with ISO 10993, as well as food contact regulations in the US and Europe.

可消毒 Sterilizable

与其他通用级树脂一样，STYRON™ 2678 MED PS 树脂可以环氧乙烷 (EtO) 消毒；而甚至在高剂量的伽玛及电子束消毒上，亦表现出非常良好的辐射稳定性。

Consistent with GPPS, STYRON™ 2678 MED PS Resins can be sterilized by ethylene oxide (EtO), and come with very good radiation stability when subjected to gamma- and e-beam sterilization - even at high doses.

抗化学性能表现 Chemical Resistance Performance

STYRON™ 2678 MED PS 树脂是为需要进行消毒的环境而设，固会被暴露于广泛的表面消毒液和清洁剂，如水、盐水、醇（如异丙醇）、酸和油脂。其抗化学性能可见下表：

STYRON™ 2678 MED PS Resins are designed for environments where they may be exposed to a wide variety of surface disinfectants and cleaners, such as water, salt solutions, alcohols (such as IPA), acids and lipids. Their chemical resistance performance is indicated in the table below.

化学品 Chemicals	稀酸 Dilute Acids	稀碱 Dilute Bases	油/油脂 Oils/Grease	矽 Silicones	碘 Betadine	IPA	环氧乙烷 Ethylene Oxide	盐水 Saline Water	漂白剂 Bleaches	过氧化氢 Hydrogen Peroxide	消毒剂 Disinfectants	肥皂/洗涤剂 Soaps and Detergents
极佳 Good	●	●				●	●	●	●	●	●	●
良好 Fair			●	●	●							

适用于二次加工方法 Finishing Methods Available

收缩度低使 STYRON™ 2678 MED PS 树脂常被用于不同的二次加工程序，如溶剂粘合（如甲苯、二氯甲烷、乙酸丁酯）、焊接（如热、超声波、激光）和激光雕刻或印花。

Its low shrinkage feature allows STYRON™ 2678 MED PS Resins to be used as a foundation for secondary operations, such as solvent bonding (e.g. toluol, dichloromethane, butyl acetate, etc.), welding (e.g. heat, ultra-sonic, laser, etc.) and laser marking or printing.

应用推介 Recommended Applications

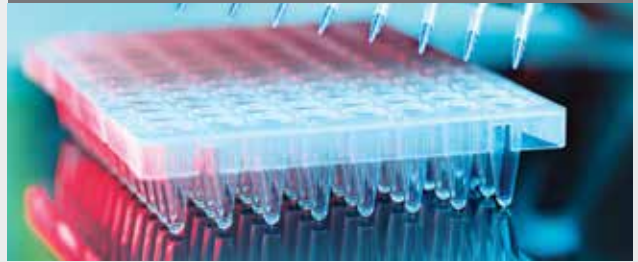
STYRON™ 2678 MED PS 树脂提供平衡性能，及注塑加工所需的工艺性能及极佳尺寸稳定性。以下是我们的应用推介：

STYRON™ 2678 MED PS Resins are specifically designed for injection-molding applications in which excellent processability and dimensional stability in a well-balanced material are required. Recommended applications include:

培养皿
Petri Dishes



移液板
Pipettes Plate



法规支援及品控程序 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.





如需了解盛禧奥提供的产品、创新、专业技术和其他服务的详细资料，请浏览本公司网站：www.trinseo.com，或按以下信息联络我们。

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The principles of Responsible Care® and Sustainable Development 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拥有一个基本原则，就是关怀所有制造、分销和使用其产品的人员以及我们生活的环境。这是我们的产品监管原则的基础，我们根据监管原则评估我们产品的安全、卫生和对环境的影响，然后采取适当措施来保护我们的员工、公共卫生和环境。我们产品监管的成功取决于与盛禧奥产品有关的每个人 - 从每件产品的构思和研究开始到制造、使用、销售、处置以至循环再生。

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.

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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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