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Trinseo Medical Grade Plastics Biocompatibility Testing Data Sheet

All of Trinseo's Commercial Medical Grade products have been evaluated for their ability to successfully pass a standard battery of biocompatibility testing. These evaluations have been conducted by the contract labs of North American Science Associates Incorporated, Northwood, Ohio (NAMSA) based on the guidelines of the International Organization of Standardization (ISO 10993). In addition, these biocompatibility studies were conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58). The table below lists the tests, with applicable test method, which Trinseo products must pass in order to be sold by Trinseo as a medical grade product.

TEST	METHOD[a]
In Vitro Hemolysis: Extraction Method	ISO 10993 Part 4/Modified ASTM
In Vitro Hemolysis: Direct Contact Method	ISO 10993 Part 4/Modified ASTM
Cytotoxicity, Elution Method	ISO 10993 Part 5
Muscle Implantation – 1 week	ISO 10993 Part 6
Guinea Pig Maximization Sensitization	ISO 10993 Part 10
Intracutaneous	ISO 10993 Part 10
Systemic Toxicity	ISO 10993 Part 11
Physicochemical Test	USP<661>

[a] ISO = International Organization of Standardization 10993: Biological Evaluation of Medical Devices
[a] ASTM = American Society of Testing Materials
[a] USP = United States Pharmacopeia

These studies are performed on pellet samples of medical grade resin. The purpose of this testing is to ascertain whether the Trinseo materials cause any health effects. This testing is intended only as a preliminary qualification step and does not take into account processes or conditions of use by the customer; instead, the medical device manufacturer is responsible for evaluating its product based upon such factors as manufacturing processes and conditions of use. Trinseo LLC does not submit any finished devices or articles for testing.

Trinseo can provide detailed information with regard to biocompatibility testing and regulatory compliance for its products. New products may require additional time for the biocompatibility evaluation. Biocompatibility and compliance letters on new products will be provided upon request after final product testing and approval is completed.

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Product Stewardship

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.

Customer Notice

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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