



# WITTENBURG

Your partner in TPE, medical & food compounds

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## **Product Stewardship Bulletin (PSB) for Cawiton TPE grades intended to be used for medical and/or pharmaceutical applications (March 2019)**

Cawiton TPE grades intended for medical and/or pharmaceutical applications comply with the relevant laws and regulations as required. Being synthetic and latex-free, these products have proven to be strong alternatives for PVC and can as such be used in medical device components, medical and pharma packaging, medical tubing, etc. In order to be fit for purpose, the materials have to meet stringent demands, including biocompatibility to the levels required for the specific use, compliance with legislative and regulatory requirements, including compliance with environmental regulations.

### **Raw materials**

All raw materials used in compounding of Cawiton TPE series of medical and pharmaceutical packaging grades are controlled for compliance with EU and USA food contact regulations, as laid down in Commission Regulation (EC) No 1935/2004; Commission Regulation (EU) 2011/10 as amended; Commission Regulation (EC) 2023/2006; US FDA CFR Code of Federal Regulations Title 21 (April 2017). To minimize any potential biocompatibility issues, the thermoplastic elastomer base resins used are selected from product series of which representative grades have passed USP Class VI tests, involving:

1. systemic toxicity to determine the irritant effect of toxic leachables present in extracts,
2. intracutaneous tests to assess the localised reaction of tissue to leachable substances, and
3. implantation tests to evaluate the reaction of living tissue to the plastic.

The usage of thermoplastic elastomers in general and Styrene Block Copolymers (SBC's) in particular is not covered by the European Pharmacopeia (EP). In case of SBC's such as SEBS, the paraffinic oil used as an extender is a medicinal white oil, which is compliant with the USP, EP and other Pharmacopeia's. Also polyolefins (PP, PE) used are predominantly medical grades that meet the compositional requirements of the European Pharmacopeia or have been tested for compliance with the EP, and/or have passed USP Class VI testing.

### **Cawiton material biocompatibility**

In addition to careful raw material selection measures, in order to increase the level of assurance for our customers, a variety of medical Cawiton products - for medical packaging film, for medical tubing, for medical stoppers and other injection-moulding applications - has been tested for biocompatibility according to ISO 10993-5 (in vitro cytotoxicity); ISO10993-10 (irritation, sensitization) and USP Class VI by various well-known accredited external laboratories. Due to the overlap between some tests in USP and ISO10993, passing USP Class VI requirements will increase the likelihood of passing specific ISO10993 parts. However, it is to be noted that it is always the responsibility of the supplier of the finished product to perform relevant tests to ensure that the complete application (package, device, etc.) fulfils the compliance criteria that have been set up for the product.

### **Manufacturing processes, Quality and Consistency**

Cawiton TPE series of materials for medical applications are all produced under strict quality control and the Zeewolde Manufacturing Site is accredited to ISO 9001 and has implemented ISO 13485. Good Manufacturing Practices implemented include a thorough and documented line clean-down; using a closed manufacturing system from the material blending stage to the packaging stage; special precautions to avoid contamination issues; usage of special clean clothing, shoe covers, gloves and hairnets in the operations area. As formulation changes may have severe consequences for medical customers, based on contractual agreement Wittenburg may implement a "No change" policy after recipe, line & process conditions fixation. Any enforced changes in supplier raw material composition and/or quality will be communicated to and discussed with our customers well in advance. Electronic data storage facilitates lot-to-lot traceability of raw materials and process conditions.



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**Please note that Wittenburg will not supply any product for applications mentioned below:**

Cawiton grades in general are not designed or manufactured for use in human body implants or in contact with internal body fluids and tissues. Wittenburg has not performed clinical testing of Cawiton grades for implantation and/or internal body fluid (tissue) contact, and makes no representation, promise, or warranty concerning the suitability of these materials for use in such applications. The decision to use our materials for a specific application is solely at the customer's own responsibility and risk, i.e. the customer is to determine that the medical device (component) or pharmaceutical or in vitro diagnostic application is safe and technically suitable for the intended use and meets all applicable legal requirements. Please note that Class III applications (according to EU Directive 2017/745/EU) as defined below are considered as "high risk" applications, for which major polymer manufacturers tend to have highly restrictive supply policies. Therefore, detailed discussions with our raw material suppliers and with you as a Wittenburg customer will be required before the decision can be taken to supply material under indemnification contract.

**'High Risk Applications'**

1. Body implant applications where materials are intended to be used for permanent implantation (more than 30 days in the body or in contact with body fluids and tissues).
2. Medical devices (components of medical devices) categorized as risk class III according to EU Directive 2017/745/EU.
3. Critical components in any medical device that support or sustain human life.

**Disclaimer**

By using any Technical Information contained herein, you agree that said technical information is given for convenience only, based on supplier information, and without any warranty or guarantee of any kind, and is accepted and used at your sole risk. As used in this paragraph, "Technical Information" includes any technical advice, recommendations, testing, or analysis, including, without limitation, information as it may relate to the selection of a product for a specific use and application.

*We need to make clear that the responsibility for the use of the final products/articles (with respect to medical and/or food contact regulations) rests entirely at the end-use manufacturer. He should ensure that his products comply with the migration and concentration requirements imposed and that it is produced under the right circumstances.*

We trust this information is conform your request and we remain,

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