

Declaration Concerning Food Contact

FDA (Food & Drug Administration)

Product: PEEK MG natural

We hereby declare that our above-mentioned product, due to the resin manufacturer's data, complies with the requirements of the FDA regulation 21 CFR, Part 177, Section 2415 „Poly(aryletherketone) resins“ concerning its chemical composition. The resin manufacturer's quality management system is certified according to ISO 9001:2015.

Scope and Restrictions

Scope: This declaration applies to natural (unfilled, unpigmented) PEEK in medical grade (MG) as a semi-finished product – sheets and round rods in the standard commercial dimensions.

Extraction limits: The extraction limits specified in 21 CFR 177.2415 relate to the finished article and the specific conditions of use (type of food, temperature, contact time). They must be confirmed by the processor on the end product.

Compliance with these requirements was not checked on the semi-finished product, as these generally relate to the final article. The exact provisions of the above-mentioned FDA regulation can be found at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

The reference to 21 CFR 177.2415 applies to the grade named. Other colourings, fillers or additive modifications of PEEK are not covered by this declaration.

Note: It is the customer's own responsibility to test the suitability of plastic items manufactured from or with our products for the planned application in the foodstuff industry. That includes for example:

- testing, if the physical characteristics of the plastic are suitable for the planned application,
- testing, if plastic parts manufactured by the customer fulfil the prescribed migration or extraction values,
- testing for possible influence of the plastic on the composition and/or organoleptic characteristics of foodstuffs.

This information is based on the information provided by our suppliers. We are not liable for the completeness and correctness of information contained herein. Existing laws and regulations must be respected by the receivers/users of our product in their own responsibility.

All information contained in this document is provided in good faith and is based on sources believed to be reliable at the time of publication of this document. In the event of changes, for example due to legislation, manufacturing-related changes, or new scientific findings, this declaration will be reassessed and becomes invalid. This declaration expires automatically 12 months after the date of issue. It is the sole responsibility of our customer to ensure that the laws and regulations necessary for their intended use are complied with. Please request an up-to-date confirmation from Liedtke Kunststofftechnik if required.

The Food and Drug Administration (FDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments.

This document is automatically generated and valid without signature.