

Declaration Concerning Food Contact

FDA (Food & Drug Administration)

Product: PPSU MG bone

We hereby declare that the polyphenylsulfone base matrix of our above-mentioned product, due to the resin manufacturer's data, complies with the requirements of the FDA regulation 21 CFR, Part 177, Section 2500 „Polyphenylene sulfone resins“ concerning its chemical composition.

Restrictions

Colouring: This is a bone-coloured PPSU grade in medical quality. Food-contact suitability of the pigmented compound is not declared in a blanket manner; it depends on the pigment used and must be confirmed case by case. According to the resin manufacturer, the material is not intended for medical devices that remain in the human body for more than 24 hours.

Conditions of use: Food-contact suitability must be confirmed separately for the specific grade used. For unambiguous food contact, virgin (unfilled, unpigmented) PPSU should be used.

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 177.2500 relates to the PPSU base matrix. For the modified compound, food-contact suitability depends on the pigment and must be confirmed case by case.

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. Food-contact suitability of the modified compound depends on the pigment and the specific grade and must be confirmed for the specific type used. 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.

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