Prohlášení týkající se styku s potravinami

FDA (Úřad pro kontrolu potravin a léčiv)

Röchling Industrial Lahnstein SE & Co. KG
Sustaplast-Str. 1 • 56112 Lahnstein/Germany (DE) • Tel. +49 2621 693-0
info.lahnstein@roechling.com • www.roechling.com/industrial/lahnstein

Produkt

SustaPEEK MOD černý

We hereby declare that our above-mentioned semi-finished product, due to the resin manufacturers data, comply with the requirements of the FDA-regulation **21 CFR, Part 177, Section 2415 „Poly(aryletherketone) resins“, as well as, if applicable, further specific FDA regulations for additives or colorants contained (e.g. FDA 21 CFR 178.3297 Colorants for polymers) .**

Druhy potravin SustaPEEK MOD black, which include carbon fibre, graphite and PTFE additives, may be used in the manufacture of articles or components of articles for repeated use in contact with food, except for infant formula and breast milk*. (*This limitation is based on the requirements indicated within the Infant Formula cGMP regulation 21CFR § 106).

Další: The finished food contact article is subject to extractive limitation as per FDA regulation 21 CFR 177.2415 (c). Compliance with the extractive limitation can only be demonstrated by tests carried out by the manufacturer of the final article who has responsibility to ensure suitability and safety for its intended use.

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 aboved-mentioned FDA-regulation can be found at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

The quality assurance system of Röchling Industrial Lahnstein SE & Co. KG is certified as per DIN EN ISO 9001:2015 and serves as an important basis of the constant composition and quality of SustaPEEK MOD černý.

Note:

It is customers 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 fulfill the prescribed migration or extraction values,
- testing for possible influence of the plastic on the composition and/or organoleptic characteristics of foodstuffs.

This information above is based on the information provided by our suppliers. We are not liable for 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, new statements will be published on our websitehttps://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/peek/sustapeek-mod-black-591048. Previous declarations will become invalid as a result. This declaration expired 12 months after the date of issue (Print). It is the sole responsibility of our customer to ensure that the laws and regulations necessary for their intended use are complied with. Therefore, if necessary, please request a new confirmation or download it from our websitehttps://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/peek/sustapeek-mod-black-591048.

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 has been printed automatically and is valid without any signature.