

Declaration concerning food contact (FDA)

Röchling Sustaplast SE & Co. KG
D-56112 Lahnstein
Tel. + 49 2621 693-0
Fax + 49 2621 693-170
www.roechling.com
info@sustaplast.de

Product: **SUSTAPEEK GLD 140 FG natural/blue**

We hereby confirm that our semi-finished products made of

SUSTAPEEK GLD 140 natural / blue

Polyetheretherketone (PEEK – ISO 1043) is compliant with applicable FDA regulations for food contact. This product is extruded by using raw materials (polymer and colorants), that is compliant for use in food contact applications according to **Federal Regulations CFR 21, part 177, paragraph 2415**, as well as, if applicable, further specific FDA regulations for additives or colorants contained (e.g. FDA 21 CFR 178.3297 Colorants for polymers).

The finished food contact article is subject to extractive limitation as per FDA regulation 21 CFR 177.2415. The safety of usage in contact with infant formula, its ingredients, and breast milk has not been evaluated. Compliance with these requirements was not checked on the semi-finished product, as these generally relate to the final article. Compliance with the extractive limit can only be demonstrated by tests carried out on the final article.

The exact provisions of § 21 CFR 177.2415 can be found at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

The quality assurance system of Röchling Sustaplast SE & Co. KG is certified as per DIN EN ISO 9001 and serves as an important basis for the constant composition and quality of **SUSTAPEEK GLD 140 natural / blue**.

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,

The 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 products in their own responsibility.

This declaration is reevaluated in case of expiry of validity, modifications of directives and laws, raw materials, formula, manufacturing procedures or other. In this cases, new declarations are published on our website www.roechling.com, earlier declarations automatically become invalid in that case.

This document has been printed automatically and is valid without any signature.

Erstellt am: 30.01.2013
Letzte Änderung vom: 09.09.2021
Druckdatum: 09.09.2021
Dateiname: SUSTAPEEK-GLD140-FG-natural-blue-FDA-compliance_Rev.02.docx

Index: 02
Seite: 1 von 1

