

Declaration of Compliance

for products made of plastic intended to come into contact with foodstuffs

Röchling Sustaplast SE & Co. KG
Sustaplast-Str. 1
56112 Lahnstein/Germany
Tel. +49 2621 693-0
Fax +49 2621 693-170
info@sustaplast.de
www.roechling.com

Product: SUSTAPEEK FG natural (PEEK)

We herewith confirm that the semi-finished product mentioned above is in compliance with the requirements of the following regulations:

- (EC) No 1935/2004 of the European Parliament and the Council dated 27th October 2004 applicable for materials and goods destined to come into contact with foodstuffs and for revocation of the directives 80/590/EEC and 89/109/EEC, Gazette of the European Communities L 338/4 dated 13/11/2004, modified by Appendix nr. 5.17 of the regulation (EC) No 596/2009 dated 18th June 2009, Gazette of the European Communities L 188 dated 18/07/2009, article 3,
- Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFBG) in the version of the notification of 22nd of August 2011 (BGBl. I p. 1770), last amendment by article 1 of the Directive of 3 August 2012 (BGBl. P. 1708), §§ 30 and 31

Furthermore the product meets the requirements of

- (EC) No 10/2011 of the Commission dated 14th of January 2011 on plastic materials and articles to come into contact with food, Gazette of the European Communities L 21/1 dated 15/01/2011, last amendments by Commission Regulations (EU) No 1282/2011 dated 28 November 2011, (EU) No 1183/2012 dated 30. November 2012 and (EU) No 202/2014 dated 03. March 2014.
- Decree on Consumer Goods in the version of the communication of 23rd of December 1997 (BGBl. 1998 I p.5), last modification by Article 5 of the Decree of 13th of December 2011 (BGBl. I p. 2720).

with regard to the composition and the migration behaviour.

The manufacturing of the product mentioned above is carried out according to the method „Good Manufacturing Practice“ (GMP), corresponding to the regulation (EC) No 2023/2006 of December 2006 applicable for the good manufacturing practice for materials and goods destined to come into contact with foodstuffs.

According to the regulation (EC) No 1935/2004, the traceability of our products is guaranteed at all levels and is carried out by means of the production number inscribed on the product label or the accompanying documents.

Testing conditions for migration tests based on the application

The product was tested according to the methods for “examination of utensils“ by means of several samples, according to the regulation B 80.30, 1 to 3 (EC) of the Official List of testing procedures according to § 64 LFBG (Germany), as well as the series of standards EN 1186, EN 13130 and CEN/TS 14234 “materials and goods in contact with foodstuffs – plastics“.

According to the general rules for migration tests, the total migration and the specific migrations of individual substances were determined by using food simulants and pre-defined testing conditions (time/temperature). The overall migration as well as the specific migration do not exceed the legal limits set out in directive (EC) No 10/2011 when used as specified in table 1.

Declaration of Compliance

for products made of plastic intended to come into contact with foodstuffs

Product: SUSTAPEEK FG natural (PEEK)

Determination of migration behavior

Testing simulant	Testing conditions (time/temperature)	Intended contact with foodstuffs
Acetic acid 3%	4 hours at 100°	Direct contact with all types of food under any temperature/time-combination
Ethanol 10 vol.%	4 hours at 100°	
Ethanol 95% as substitute for fat	6 hours at 60°C (substitute test for 2 hours at 175°C)	
Isooctan as substitute for fat	4 hours at 60°C (substitute test for 2 hours at 175°C)	

Ratio of the surface in contact with the foodstuff to volume (S/V), used to determine the compliance of the material:

$$\frac{F}{V} = 6 \text{ dm}^{-1}$$

The following substances with restrictions and/or specification are used in the product mentioned above:

Name of the substance	FCM substance No	Restrictions
4,4-diflourobenzophenone	337	SML = 0,05 mg/Kg
diphenyl sulphone	313	SML(T) = 3,00 mg/Kg
1,4-dihydroxybenzene	295	SML = 0,60 mg/Kg

SML = specific migration limit in food or in food simulant

QMA = max. permitted quantity in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs.

The following substances*, which are also approved as food additives („Dual use“), may be contained in the product mentioned above:

Name of the substance

* as far as information concerning this point is included in the conformity documents made available by the raw material producer

Product: SUSTAPEEK FG natural (PEEK)

Declaration of Compliance

for products made of plastic intended to come into contact with foodstuffs

The quality SUSTAPEEK FG natural can be used safely for the manufacture of finished products for companies which are preparing and processing foodstuffs. The finished products may stand in direct contact with all types of food as far as the SUSTAPEEK FG natural is concerned. The permitted surface to food mass ratio is 6 dm²/Kg food. It is important that the above mentioned contact times and temperatures are not exceeded.

General Information

The formulas of the materials listed in the declarations of conformity have been subjected to extensive migration tests with different stimulants by an independent accredited institute in compliance with EU 10/2011. The tests were carried out on mechanically processed samples of our semi-finished products.

Furthermore, it has been assured that generally only such raw materials are used for the material where the appropriate verifications of suitability (supporting documents) have been provided by the raw material supplier or that can be disclosed to an approved third party (test institute/laboratory) by means of an agreement of confidentiality on the part of the raw material supplier.

It remains the responsibility of the customer to determine the suitability of the plastic articles produced from or with our products for their intended use or rather under the respective conditions of use (contact time, contact temperature for the respective type of foodstuff). In addition to the general suitability for use of the material (e.g. chemical resistance to the cleaning agent used), such responsibility also includes observation of the migration limits in the event the actual contact conditions exceed or deviate from the "intended food contact" laid down in our declaration of conformity.

The products mentioned, are not suitable for medical or dental applications.

Organoleptic Testing:

In the case of coloured grades (all materials not of natural colour), determination of colour fastness was carried out in accordance with the method for testing the colour fastness of articles intended to come into contact with foodstuffs that are made of coloured plastic and other polymers, 24th Communication on the testing of plastics: Bundesgesundheitsblatt 15, 285 (1972). 3% acetic acid, 10% ethanol, 95% ethanol as substitute for fat and Isooctan as substitute for fat were used as test stimulants. Result: the colouring is colourfast when in contact with all test stimulants.

Organoleptic (odour, taste) tests were not carried out, as a representative selection of suitable test foodstuffs and their corresponding contact parameters (temperature/time) on our level of the process chain is practically impossible due to the virtually unlimited combination possibilities of foodstuffs and contact conditions.

The above-mentioned information is based on the current state of our knowledge (see date of issue or change in the footer). It is the responsibility of the recipient/user of our products to ensure that all existing laws and regulations are observed. This declaration will be reassessed in the event of any changes in laws, regulations and directives, raw materials, formulas, processing procedures or the like.

On request of the customer our semi-finished products can be finished in our in-house cutting department. This declaration covers semi-finished products in the above-mentioned quality that can be cut to the desired size by means of sawing and/or planing (without the use of cooling lubricants). Cooling lubricant is used during grinding. The impact of the cooling lubricant on the migration properties was not tested in our process stage; this should be taken into consideration in the downstream process step.

Liability claims against the issuer of this declaration of conformity related to damage of a material, immaterial or ideal nature and caused by the usage or non-usage of the information offered or by the usage of defective and/or incomplete information are excluded on principle.

*In the event of changes new declarations are published on our website www.roechling.com, earlier declarations are then automatically rendered invalid.

Röchling High-Performance Plastics

This document is automatically generated and valid without signature.