

Declaration of Compliance

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

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Product: SUSTAPEEK natural, SUSTAPEEK FG natural (PEEK)

We herewith confirm that the semi-finished product SUSTAPEEK natural, SUSTAPEEK FG natural, as a product from intermediate stage of manufacture, 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 31 August 2015 (BGBl. P. 1474), §§ 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 174/2015 dated 05. February 2015, Gazette of the European Communities L 30/2 dated 06.02. 2015, Chapter II, III and V.
- Decree on Consumer Goods in the version of the communication of 23rd of December 1997 (BGBl. 1998 I p.5), last modification by Article 1 of the Decree of 24th of June 2013 (BGBl. I p. 1682).

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(OML/SML).

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Table 1 - Determination of migration behaviour

Testing simulant	Testing conditions [OM7]	Intended contact with foodstuffs
Acetic acid 3%	4 hours at 100°C repeated contact °	Single and repeated contact up to 30 days at room temperature or below, including a heating up to 100 °C for up to 4 hours or up to 121 °C for up to 1 hour for all kinds of food, as well as contact at 175 °C for up to 2 hours with foodstuffs, which have to be tested with simulant D2
Ethanol 10 vol.%	4 hours at 100°C repeated contact	
Ethanol 95% as substitute for fat	30 hours at 60°C repeated contact	
Isooctan	10 days at 60°C repeated contact	

The maximum permissible ratio of plastic surface to quantity of foodstuff is:

- 10 dm² / kg food

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

Name of the substance	CAS No	Restrictions
4,4-diflourobenzophenone	0000345-92-6	SML = 0,05 mg/Kg
diphenyl sulphone	0000127-63-9	SML(T) = 3,00 mg/Kg
1,4-dihydroxybenzene	0000123-31-9	SML = 0,60 mg/Kg

OML= Overall Migration Limit (< 10mg/dm²)

SML= Specific Migration Limit

SML(T) = Total Specific Migration Limit

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

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

The semi-finished quality SUSTAPEEK natural * and 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 single or repeated direct contact with all types of food, as far the quality SUSTAPEEK natural or SUSTAPEEK FG natural is concerned.

It is important to ensure that the above-mentioned contact times and temperatures as well as the maximum permissible surface food ratio are not exceeded.

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* Note:

This declaration serves as a supporting document for next processing stage. Our evaluated semi-finished product (product from intermediate stage of manufacture) or construction parts made of these semi-finished products is basically suitable for use in contact with foodstuffs.

Proper further processing and proper use, however, are the responsibility of the user or the end user of the material, since these steps are beyond our control. In order to prove that the material described may come into contact with food, including the proper use, we have carried out tests exclusively on semi-finished products, as we are not aware of the application-specific conditions of use. Manufacturers or distributors of finished articles should arrange their own evaluations.

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 according date of issue or change in the footer and on external laboratory Report no. 5586/29 and COC 41491U15. 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.

** This confirmation expires after 24 months after the date of issue or in case of regulatory changes. It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed. Therefore we urgently ask you in your own interest to regularly check the confirmations issued on our website with respect to modifications or changes. In the event of changes new declarations are published on our website www.roechling.com, the former certificates automatically become void earlier.*

Röchling Sustaplast SE & Co. KG

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