Declaration of Compliance

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

Publisher, Manufacturer:

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Product

SustaPEEK GLD 140 FG natural

We herewith confirm that the semi-finished product made from the material 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 13th November 2004, last amendment by the Article 5 of Regulation (EU) 2019/1381 of 20th June 2019, Gazette of the European Communities L 231/1 of 06th September 2019, Article 3, paragraph 1 a) and b)
- Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) in the version of the notification of last amendment by article 2 of the Directive of 20th December 2022 (BGBI. I S. 2752), §§ 30 and 31

Furthermore, the product meets the requirements of

- (EC) No 10/2011 of the Commission dated 14th January 2011 on plastic materials and articles to come into contact with food, Gazette of the European Communities L 21/1 dated 15th January 2011, last amendments by Commission Regulations (EC) No 2023/1627 of 10 August 2023, Official Journal of the European Union L 201/4 of 11.08.2023, Chapter II, III and V

regarding 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 does not exceed the legal limits set out in directive (EC) No 10/2011 when used as specified in table 1.

Table 1 - Determination of migration behavior

Testing simulant	Testing conditions	Intended contact with foodstuffs
Acetic acid 3 %	4h with reflux, repeated contact [OM6]	Single and repeated contact up to 30 days at room temperature or below, including heating up to heating up to 100 °C for up to up to 4 hours for all types of food foods and the heating of foods of foodstuffs to which only assigned to simulant D2 to up to 175 °C for up to 2 hours
Ethanol 10 vol.%	4h with reflux, repeated contact [OM6]	
Ethanol 95% as substitute for fat	30 hours at 60°C , repeated contact [OM6]	
isooctane as a substitute for fat	10 days at 60°C , repeated contact[OM6]	

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

10 dm²/kg

Information on substances used or their degradation products for which Annexes I and II of Regulation EU 10/2011 contain restrictions and / or specifications

CAS Name	Restrictions
4,4′-difluorobenzophenone | Monomer | Ref. No. 15820 | CAS No. 0000345-92-6	SML = 0,05 mg/kg
1,4-dihydroxybenzene | Additive | Ref. No. 15940 / 18867 / 48620 | CAS No. 0000123-31-9	SML = 0,6 mg/kg
tetrafluoroethylene | Monomer | Ref. No. 25120 | CAS No. 0000116-14-3	SML = 0,05 mg/kg

In addition, further specifically limited substances and/or dual-use additives are included, which are subject to confidentiality by the manufacturer

OML = total migration (OML) <10mg / dm²
SML = specific migration limit in food or in food simulant
SML(T) = Total Specific Migration Limit
QMA = max. permitted quantity in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs.

Dual Use

The following substances, which are also approved as food additives („Dual use“), may be contained in the product mentioned above (EC directives 89/107/EEC, 95/2/EC):

Dual-use additives may be contained, which are subject to confidentiality by the manufacturer

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

NIAS (non-intentional added substances)

As part of the conformity assessment, studies on non-intentional added substances (NIAS) were performed by means of GC-MS screenings on representative selected test samples.

CAS Name	Basis for the assessment	Limitation
acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22) | Additive | Ref. No. 31335 | CAS No. —	Article 3, paragraph 1 b) of Regulation (EC) No 1935/2004	60 mg/kg

Functional Barrier

Use of a functional barrier acc. Regulation (EU) No 10/2011 Article 3: None

Result

The quality SustaPEEK GLD 140 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 the quality SustaPEEK GLD 140 FG natural is concerned.

As far as the above-mentioned PEEK quality is concerned, end products manufactured with it may come into contact with all types of food for 30 days at room temperature or below, including heating up to 100 °C for up to 4 hours. In addition, heating of foods to which only simulant D2 is assigned up to 175 °C for up to 2 hours is safe.
The permissible ratio of plastic surface area to food volume is up to 10 dm²/kg for single and repeated contact with the food.It is important that the above-mentioned contact times and temperatures are not exceeded regarding the Regulation (EU) No 10/2011.

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General Information

This declaration serves as a supporting document for the downstream user. Our semi-finished materials or cuts from these semi-finished materials are products from intermediate stages of production in accordance with Regulation (EU) 10/2011, Article 15 and are not consumer goods in the sense of the Bedarfsgegenständeverordnung (§ 2) and the Lebensmittel- und Futtermittelgesetzbuchs (§ 2 Abs. 6 Satz 1 Nr. 1), as well as Regulation EC/1935/2004, Article 1, Para. 2.

The formulations of our materials listed in the declarations of conformity have been subjected to extensive migration tests with various simulants in accordance with EU 10/2011 at an independent accredited institute. 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 the raw material supplier discloses its ingredients to a suitable third party (testing institute/laboratory) by means of a confidentiality agreement.

The material is basically suitable for use in contact with food under the aforementioned conditions. However, since we do not know the conditions of use of the finished articles, it remains the responsibility of the customer to determine the suitability of the plastic

articles (consumer goods) 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 aforementioned products 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 and Isooctan as substitute for fat were used as test stimulants. Result: the colouring is colourfast when in contact with all test stimulants.

Odor and taste tests were omitted, because due to the almost unlimited possibility of combining foods and contact conditions, a representative selection of suitable test foods and associated contact parameters (temperature/time) cannot be practically guaranteed at our stage of the process chain.

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.

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 website https://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/peek/sustapeek-gld-140-fg-natural-591275 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 website https://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/peek/sustapeek-gld-140-fg-natural-591275

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