

CERTIFICATE OF COMPLIANCE

GEHR® PEEK natural - round rods and extruded sheets

Tested on the semi-finished product

Food contact

European Directives	EU/1935/2004, EU/10/2011 as amended, Test report on request.
Dual use additives	E 572 Calcium Stearate: Check of final articles for overall migration limit which may not exceed 60 mg/kg of food or 10mg/sq dm of surface area of article
'GMP' Good manufacturing practice	GEHR complies with the GMP Directive EU/2023/2006 through the quality management system, which has been introduced and implemented in accordance with the current requirements of DIN EN ISO 9001.

Tested on the raw material

These confirmations are based on statements of the raw material supplier.

Food contact

Food & Drug Administration	FDA (CFR 21, 177.2415), The raw material is, therefore, permitted by FDA for use as articles or components of articles intended for repeated use in contact with food. All additives contained are FDA compliant and are not subject to restrictions beyond those listed in 21 CFR Part 177.2415.																												
US, dairy equipment	3A Sanitary Standard Procedure 20-27																												
EU regulation on food contact	<p>As specified below the substances used to manufacture this product meet the requirements of Commission Regulation EU/10/2011, which implements the framework regulation EU/1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact as related to plastic materials and articles intended to come into contact with food and its subsequent amendments ("the framework Regulation"), as well as current GMP requirements set forth under the framework Commission Regulation EU/2006/2023 of December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.</p> <p>All monomers and additives used for the manufacture of this resin are listed in the "Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids." (Annex 1 to Commission Regulation EU/10/2011).</p> <p>Specific migration limits must be met by the final articles coming into contact with food for the following monomers and additives:</p> <table><tr><th>Reference No.</th><th>CAS No.</th><th>Substance name,</th><th>SML</th></tr><tr><td>15820</td><td>345-92-6 4,4'</td><td>Difluorobenzophenone,</td><td>0.05 mg/kg</td></tr><tr><td>15940, 18867</td><td>123-31-9</td><td>Hydroquinone</td><td>0.6 mg/kg</td></tr><tr><td>89040</td><td></td><td>Stearic Acid,</td><td>No SML establ.</td></tr><tr><td>16650, 51570</td><td>127-63-9</td><td>Diphenyl Sulfone,</td><td>3 mg/kg</td></tr></table> <p>Dual Use Additive:</p> <table><tr><th>Reference No.</th><th>CAS No.</th><th>Substance name,</th><th>SML</th></tr><tr><td>E572</td><td></td><td>Calzium Stearat</td><td></td></tr></table>	Reference No.	CAS No.	Substance name,	SML	15820	345-92-6 4,4'	Difluorobenzophenone,	0.05 mg/kg	15940, 18867	123-31-9	Hydroquinone	0.6 mg/kg	89040		Stearic Acid,	No SML establ.	16650, 51570	127-63-9	Diphenyl Sulfone,	3 mg/kg	Reference No.	CAS No.	Substance name,	SML	E572		Calzium Stearat	
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Japan, Japanese Food Sanitation, Positive list system

Final articles must also be checked for overall migration limit which may not exceed 60 mg/kg of food or 10 mg/sq dm of surface area of article. Please be advised that the supplier has not conducted any migration testing to determine if our resin meets these migration limits.

Please be aware of Commission Regulation EU/1245/2020, which amends and corrects Regulation EU/10/2011 and was effective September 2020. A risk assessment has been performed on this product in order to determine compliance with Art. 3 of Regulation EU/1935/2004. Such assessment was made following the provisions set out in Article 19 of Regulation EU/10/2011.

It is the responsibility of the customer that all conditions and specifications outlined under the above mentioned regulation are met and the articles fabricated from the above mentioned grade are acceptable for use in their intended food contact applications.

This statement expires in April 2026.

This letter is in response to your recent inquiry concerning the listing of this product on the Positive List System according to the amendment of Food Sanitation Law in Japan, CAO (Cabinet Office) notification No. 128 promulgated on September 27, 2024, under the law No. 46 of June 13, 2018.

Please be advised that the monomers of the base polymer used to manufacture this product are included in the polymer group 1 of Base Materials Positive List published on December 25, 2024. In addition, the additives used in this formulation are listed on the Additives Positive List and are used below the required threshold limit for this polymer group 1 or are exempt from the regulation. Inorganic compounds and Impurities are exempt from the regulation.

It is the responsibility of the customer to determine that all conditions and specifications are met and that the products fabricated from these materials are acceptable for use in their intended food contact applications. *This confirmation is valid until May 20, 2026.*

PR China, Chinese food contact regulations

This product has been formulated and manufactured in accordance with the requirements of the following China food contact recommendations or regulations:

GB 4806.1-2016 National Food Safety Standard
GB 4806.7-2023 National Food Safety Standard
GB 9685-2026 National Food Safety Standard
GB 31603-2015 National Food Safety Standard

This material has restrictions defined by relevant regulations as below table.

General Category	Substance Identity (Chemical name & CAS No.)	Limitations
PEEK	Name: Methanone, bis(4-fluorophenyl)-, polymer with 1,4-benzenediol CAS No.: 29658-26-2	SML: 0.05 mg/kg (4,4'-Difluorobenzophenone); 0.6mg/kg (1,4-Dihydroxybenzene)

It is the responsibility of the distributor of the final article to determine if all articles made of this product are suitable for the intended use and comply with all applicable regulations and requirements.

Drinking water

US, National Sanitation Foundation

NSF-61, Potable Water

UK, British Standard

NSF-14, Plumbing System Components

BS 6920 – WRC (WRAS), valid until Dec. 2025, approval No. 2012502

Special Declarations

REACH, SVHC

Conform to EU/1907/2006, see also specific Gehr conformation

ASTM 8033-22

Classification: PEEK 0111

Japan CSCL – inventory of Existing and New Chemical Substances	Listed on inventory
China IECSC – inventory of Existing Chemical Substances	Listed on inventory
Conflict materials, Dodd Frank Act TSCA	Compliant, see also specific Gehr confirmation Compliant, listed as active on the TSCA inventory, see also specific GEHR confirmation, status as amended
US California Safe drinking water & toxic enforcement act, 'California Proposition 65'	The raw material does not contain any chemicals known to state of California to cause cancer, birth defects or any reproductive harm. The raw materials used (polymer, colon batch) comply with the requirements of California Proposition 65 and do not require a warning statement under normal use conditions. Status as amended.
Bovine/Transmissible Spongiform Encephalopathy (BSE/TSE), ADI, Vegan	Substances from animal origin and animal by-products (eggs, milk, honey, beeswax, etc.) have not been intentionally added to the product and therefore are not expected to be present.
Ozon depleting substances regulation ,ODS'	Not applicable, this product is not subject to the requirements of EU/1005/2009 on ozone depleting substances.
Packaging and Packaging Waste Directive API 6A 20 th Edition and ISO 10423:2009	EU/2018/852 amending EU/94/62, US CONEG Test Certificate: APT-TC-160427-04 Test certificate on request Not valid for rods with diameter 5 & 6 mm and filaments. M-710 Rev.2
Norsok (Qualification of non-metallic sealing materials and manufacturers) 'End of life vehicles'	Directive EU/525/2002 amending Directive EU/53/2000 ("End of life vehicles") as related to the content of Cadmium or Cadmium compounds, Lead, Mercury and hexavalent Chromium.
ASTM D-6262	The raw material meets the requirements of ASTM D-6262, the classification is S-PAEK 0111
Aerospace Approvals	
EU, Airbus	AIMS04-01-02 Issue 4 IPS04-01-012-02 Issue 1
PR of China, Commercial Aircraft Corporation of China 'COMAC'	CMS-PL-906
Electrical and Electronic Devices	
RoHS, On the restrictions of the use of certain hazardous substances in electrical and electronic equipment	Directive EU/2102/2017 amending Directive EU65/2011 of the European Parliament and of the Council of 8 June 2011 ("on the restrictions of the use of certain hazardous substances in electrical and electronic equipment") as related to the content of Cadmium or Cadmium compounds, Lead, Mercury and hexavalent Chromium, Polybrominated Biphenyl's (PBB), Polybrominated Diphenylethers (PBDE), Bis(2-Ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP).
PR of China RoHS 2.0-GB/T 26572-2011	The requirements for concentration limits for certain restricted substances in electronic and electrical products which defines the limitations of hazardous substances: Cd<0,01%, Hg<0,1%, Pb>0,1%, Cr(VI)<0,1%, PBB<0,1%, PBDE<0,1%
Substances of Concern	
CMR 'carcinogenic, mutagenic and reprotoxic' substances	Compliant with EU/1272/2008, amended by EU/2020/1182, CMR category 1A/1B substances listed in Part 3 of Annex VI are not intentionally added or used in the manufacture of this product.
Heavy metals	Directive EU/62/94 and its amendments, not applicable Cadmium, hexavalent chromium, lead and mercury have not been intentionally added or used during the manufacturing process.
Heavy Metals CONEG	Cadmium, hexavalent chromium, lead and mercury have not been intentionally added or used during the manufacturing process.
Resolution MEPC.269(68)-2015	Guidelines for the Development of the Inventory of Hazardous Materials
Nanomaterials	Inventory declaration of Nanomaterials: Belgium & France

POP, Persistent Organic Substances	This product is not a nanomaterial and does not contain any nanomaterials per the Belgium / France definition. Not applicable, this product is not subject to the requirements of EU/850/2004 on persistent organic pollutants.
Safety of toys	Directive EU/48/2009 for Safety of Toys This product is not intended for toys.
40 CFR 51.100(s) - Definition - Volatile Organic Compounds (VOC) Exemptions	This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.
40 CFR § 704.20 - Chemical substances manufactured or processed at the nanoscale	This product is not a nanomaterial and does not contain any nanomaterials per the US EPA definition.
Flammability	
Burning behaviour	FAR 25.853 Teil 1
Smoke development	ASTM E 662
UL 94	Flame class Test specimen ≥ 1,5 mm V0 Test specimen < 1,5 mm V1
Plastics – Smoke generation	DIN EN ISO 5659-2, Determination of optical density by a single-chamber-test
Substances not used	
Alkylphenol Ethoxylates / Nonylphenol Ethoxylates (APE/NPE)	Alkylphenol Ethoxylates are not intentionally added to the product and therefore are not expected to be present.
Arsenic	Arsenic is not intentionally added or used in the manufacturing process. Therefore, it would not be expected to be present in this product.
Asbestos	
Azo dyes	Is not intentionally added to the product and therefore are not expected to be present.
Biocides	EU/528/2012, not intentionally added
Bisphenol A	Is not intentionally added to the product and therefore is not expected to be present.
Cadmium	Not expected to be present in this product
Copper	Copper is not intentionally added or used in the manufacturing process. Therefore, it would not be expected to be present in this product.
GADSL: Global Automotive Declarable Substance List	This product does not intentionally contain any of the substances on this list.
Mercury	To the best of their knowledge Mercury is not contained in nor added to the resin or additives. Therefore, we would not expect Mercury to be present.
Melamine	Melamine (CAS# 108-78-1) is not contained in nor added to the resin or additives in this product, it is not expected to be present. However, no analyses is done for these substance in relevant raw materials or finished product to determine if any unintended substance or impurities may exist.
PAH's	Is not intentionally added to the product and therefore is not expected to be present.
PCB's	Is not intentionally added to the product and therefore is not expected to be present.
PFOA / PFOA related substances	As defined in Annex XVII of Reach (entry 68), are not intentionally used in the production of the raw material.
Phthalates	Phthalates have not been intentionally added to the product and therefore they are not expected to be present.
PVC	Is not intentionally added to the product and therefore is not expected to be present.
Red Phosphorus	Is not intentionally added to the product and therefore is not expected to be present.
Rubber / Latex	Natural rubber latex (CAS# 9006-04-6) is not intentionally added during the manufacture of this product, nor is it processed with additives derived from natural rubber latex.
Silicone	Is not intentionally added to the product and therefore is not expected to be present.
Titanium Dioxide	Titanium dioxide (TiO ₂) is not intentionally added or used in the manufacturing process of the above products.

Military Conformities

USA

MIL P-46183 T 1:

this standard describing the requirements on a PEEK polymer is no more actively used by the US military. The requirements are tested by the polymer supplier based on adequate ASTM methods. The product meets the requirements of the former MIL P-46183 Type I.

We would like to point out that the testing of the overall migration limit and all other specific migration limits, e.g. delivery of special substances in measurable quantities of food or food simulants, is the responsibility of the manufacturer of the end product (distributor).

The information given in this COC is intended to inform about the regulatory status of the semi-finished articles and the raw materials they are made of. This information is not legally binding or meant as a guarantee or condition of sale. GEHR takes no warranty for the correctness or completeness of the information. It is the customer's responsibility to test and assess the suitability of the GEHR® products for an application or for the use in a finished device. GEHR® products (including MEDIGEHR® products) are not intended for medical implants, regardless of the application duration. The MEDIGEHR® products are suitable only for medical and pharmaceutical applications with direct body contact with tissues, bones and mucous membranes up to 24 hours. In the event of changes in the material formulation or legal requirements, this certificate expires. Customers should check the regulatory status regularly if necessary. This document was created electronically and is valid without a signature.