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# DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD ([1])

**Date of issue:** 19 August 2026 ([2])

**Mitsubishi Chemical Advanced Materials N.V.**
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**Galgenveldstraat 12**
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The issuer of this declaration and manufacturer of the products concerned hereby confirms that the products:

## "Ketron™ 1000 FG PEEK natural" [PEEK]

**Semi-finished products: round rods, tubes** and **plates** ([3]) **and**
**Finished parts machined from these semi-finished products by Mitsubishi Chemical Advanced Materials**

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## European Union and China

The above mentioned products

- **comply with the requirements of the articles 3, 11(5), 15 and 17 of the Regulation (EC) No 1935/2004,**
- **comply with the relevant requirements of the Regulation (EU) No 10/2011 as amended up to and inclusive of the Commission Regulation (EU) 2026/1380,**
- **comply with the requirements of GB 4806.1 - 2016**
- **comply with the relevant requirements of GB 9685 - 2016 and GB 4806.7 - 2023 and their relevant announcements,**
- **are manufactured according to Good Manufacturing Practice (GMP) as set out in Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.**
- **are manufactured according to Good Manufacturing Practice (GMP) as set out in GB 31603-2015.**

Based on migration tests performed on the products according to Regulation (EU) 10/2011 as amended, GB 4806.7 - 2023, GB 5009.156 - 2016 and GB 31604.1 – 2015, the sensory index, the overall migration, potassium permanganate consumption, heavy metal fraction as well as the specific migration does not exceed the legal limits set out in Regulation (EU) 10/2011 and GB 4806.7 - 2023, **when used as specified below**.

Specifications on the intended use of the products:

- Type(s) of food intended to come into repeated contact with the material:
  ***All types of food***
- Type(s) of food NOT intended to come into repeated contact with the material:
  ***Not applicable***

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- Time and temperature of treatment and storage when in contact with the food:

  - ***Overall migration tests run under the standardised testing conditions***
    ***10% ethanol (v/v) (4 h at reflux temperature),***
    ***50% ethanol (v/v) (4 h at reflux temperature),***
    ***3 % acetic acid (w/v) (4 h at reflux temperature)***
    ***4 % acetic acid (w/v) (4 h at reflux temperature) and***
    ***vegetable oil (2 h at 175 °C)***

  - ***Specific migration tests run in***
    ***3 % acetic acid (4 h at reflux temperature),***
    ***4 % acetic acid (4 h at reflux temperature),***
    ***10 % ethanol (4 h at reflux temperature),***
    ***50 % ethanol (4 h at reflux temperature) and***
    ***Vegetable oil (2 h at 175 °C)*** [1]

- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the products:

  ***S/V = 6 dm²/kg***

The results of the overall migration test are expressed in the table below:

| 10% ethanol (v/v) | 50% ethanol (v/v) | 3% acetic acid (w/v) | 4% acetic acid (w/v) | Vegetable oil |
|---|---|---|---|---|
| 0.8 mg/dm² | 0.5 mg/dm² | 0.8 mg/dm² | 0.7 mg/dm² | < 1.0 mg/dm² |
| | | | | |

The following substances, subject to restrictions under Regulation (EU) 10/2011 as amended, GB 4806.7 – 2023 and GB 9685-2016, are used in the products:

| Chemical name of the substances | Restrictions |
|---|---|
| 4,4'-Difluorobenzophenone (CAS No 345-92-6) | SML = 0.05 mg/kg |
| 1,4-Dihydroxybenzene (CAS No. 123-31-9) | SML = 0.6 mg/kg |
| Diphenyl sulfone (CAS No 127-63-9) | SML = 3 mg/kg |
| Proprietary substances ([4]) | |
| | |

The following substances, identified as dual use additive under Regulation (EU) 10/2011 as amended, are used in the products:

| Chemical name of the substances |
|---|
| Calcium stearate |
| Proprietary substances ([4]) |
| |

A risk assessment of Non-Listed Substances (NLS), such as catalysts and Non-Intentionally Added Substances (NIAS), such as reaction and degradation products has been performed in accordance with Article 3 of the Framework Regulation ((EU) 1935/2004), Article 19 of the Plastic Regulation ((EU) 10/2011) and Article 3.5 of GB 4806.1 - 2016, based on the conditions mentioned above.

[1] Specific migration tests in vegetable oil (2 h at 175 °C) being replaced by tests in isooctane (4 h, 60 °C), 95 % ethanol (6 h, 60 °C) and MPPO (2 h, 175°C) in accordance with Directive 82/711/EEC as vegetable oil is technically not feasible with the used methods of analyses.

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## United States

We hereby provide the following information on the compliance status of the Mitsubishi Chemical Advanced Materials stock shapes mentioned above, as set out in the regulations that apply in the United States of America (FDA) for plastic materials and articles intended to come into contact with foodstuffs:

- **Ketron 1000 FG PEEK natural** complies with the compositional and extraction requirements of the FDA regulations 21 CFR § 177.2415 “Poly(aryletherketone) resins".
  **Ketron 1000 FG PEEK natural stock shapes** may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all food types I to IX, except with infant formula and breast milk, under all conditions of use A to H as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

## Japan

Based on the compliance status of **the raw materials** used at present by Mitsubishi Chemical Advanced Materials for the manufacture of the stock shapes mentioned above, **with respect to their composition**, as set out by the Japan’s Ministry of Health, Labour & Welfare (MHLW) in the Official Notification (Notification No. 324 of 2023) of 30 November 2023 for utensils, containers and packaging intended to come into contact with foodstuffs:

- **Ketron 1000 FG PEEK natural** complies with the compositional requirements of the ‘Base materials’ and ‘Additives’ Japan food contact positive lists, as published by Japan’s Consumer Affairs Agency on 27 September 2024.
  Based on their composition, **Ketron 1000 FG PEEK natural stock shapes** may basically be used for the manufacture of articles or components of articles intended for food-contact use with all food types, under maximum temperature conditions III.

It remains the responsibility of the customer putting the plastic articles manufactured from the products into the intended use, to assess the final suitability of the plastic material for the intended food contact application; i.e. checking if the physical properties of the plastic material make it suitable for the intended application, checking compliance of the finished plastic articles with the relevant migration limits, checking for possible influence of the plastic material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

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(1) Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – Article 16 and National Standard for Food Safety GB 4806.1 - 2016 General safety requirements for food contact materials and articles– Article 2.1.

(2) This declaration expires 5 years after its date of issue or in case of compositional changes which require its re-evaluation.

(3) For information about the available dimensions, please contact your Mitsubishi Chemical Advanced Materials sales office.

(4) Substances subject to restrictions under Regulation (EU) No 10/2011 as amended are used in the products. Upon request, the identity of these substances can be disclosed to third parties (e.g. test laboratories) under the terms of a Non-Disclosure Agreement.

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NOTES:

- Finished food contact articles shall be manufactured such that the surface skin(s) of the semi-finished products is (are) taken away.
- It remains the responsibility of the customer putting the plastic articles manufactured from the products into the intended use that in accordance with good manufacturing practice, finished food contact articles are thoroughly cleansed prior to their first use in contact with food.
- This declaration of compliance is only valid for products that are carrying the Mitsubishi Chemical Advanced Materials “for food contact label” (sticker), the relevant Mitsubishi Chemical Advanced Materials “trade name label” (sticker) and the label (sticker) carrying the unique ‘production order number’ that allows traceability. For finished parts these stickers can be on the product itself or on their packing.
- It is the responsibility of the buyer to assure the traceability of the material during any further downstream use up to and including the finish machined part as well as the equipment in which it is assembled.

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**Ketron™** is a trademark of the **Mitsubishi Chemical Advanced Materials Group**.

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