

## DECLARATION OF COMPLIANCE FOR SEMI-FINISHED PRODUCTS INTENDED TO COME INTO CONTACT WITH FOOD

Date of issue: March 2023 <sup>1)</sup>

Vink Plast ApS hereby declare that:

### PTFE G400 Natural FCM round rods, plates and tubes and finished parts machined from these products by Vink Plast ApS <sup>2)</sup>:

- Comply with the requirements of the regulation (EC) no. 1935/2004 of 27 October 2004
- Comply with the relevant requirements in Regulation (EU) 10/2011 as amended up to and inclusive the commission Regulation (EU) no 2020/1245. It can be used as specified below <sup>3)</sup> based on migration tests (overall migration as well as the specific migration) performed on material with simulants below identified.
- Is manufactured and handled according to good manufacturing practice (GMP) as set out in the (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Is suitable to be used in contact with foodstuffs in accordance with US legislation – FDA 21 CFR 177.1550 “Perfluorocarbon resins”
- Is suitable to be used in contact with foodstuffs in accordance with Chinese Standard:
  - GB 4806.1-2016, General safety requirements for food contact materials and articles.
  - GB 4806.6-2016, Food contact plastic resins. The following substances is subject to restriction under GB 4806.6-2016: Tetrafluoroethylene (CAS 116-14-3), SML = 0,05 mg/kg. Specific migration limit is not exceeded for final material at following test conditions: 4 % acetic acid for 4 hours at 100 °C, 50 % ethanol for 4 hours at 100 °C, 50% ethanol for 4 hours at 100 °C and rectified olive oil for 2 hours at 175 °C.
  - GB 4806.7-2016, Food contact plastic materials and articles. The final material does not exceed the limits set out in GB 4806.7-2016 on sensory index, decoloring testing, potassium permanganate consumption, heavy metal fraction and overall migration. Overall migration limit is found below 10 mg/dm<sup>2</sup> at following test conditions: 4 % acetic acid for 4 hours at 100 °C, 50 % ethanol for 4 hours at 100 °C and rectified olive oil for 2 hours at 175 °C.
  - GB 9685-2016, Standard for use of additives in food contact materials and articles. Raw material is compositional compliant with GB 9685-2016.
- Comply with article 19 of EU 10/2011: Assessment of non-intentionally added substance – NIAS – not included in the Union list.
- There are no dual-use additives present in the material.
- Ingredient of PTFE is in “Positive List for food contact materials and articles made of synthetic resins” dated 1<sup>st</sup> June 2020 issued by the Japanese Ministry of Health, Labour and Welfare (MHLW) relative to list of the particular polymers and materials considered acceptable for use in food contact applications.
- Declaration 681/2020/DK

<sup>3)</sup> Specifications on the intended use:

- Type(s) of food intended to come into repeated contact with the material:
  - **All types of food: Aqueous, acidic, alcoholic, oily or fatty foodstuffs**
- Type(s) of food not intended to come into repeated contact with the material:
  - **Not applicable**
- Test conditions:
  - Overall migration + Colouring migration + Specific migration of primary Aromatic Amines + Specific migration Tetrafluoroethylene + Specific migration of Metals: Ba, Co, Mn, Zn, Cu, Fe, Li, Al, Ni, Hg\*, As\*, Cr\*, Pb\*, Cd\*, La\*, Eu\*, Gd\*, Tb\*
    - \*= according to Reg. EU 1245/20 (15<sup>th</sup> amendment).

Simulant A: Ethanol 10 % v/v – 4 hours at 100 °C

Simulant B: Acetic Acid 3 % W/v in aqueous solution – 4 hours at 100 °C  
 Simulant D2: Rectified olive oil – 2 hours at 175 °C

Migration test was carried out by Total Immersion.

Surface (dm<sup>2</sup>): 1.0 (4 pieces)

Volume (dl) 1

LOD: 1 mg/dm<sup>2</sup>

With reference to specific migrations, the compliance computations have been arranged assuming that 1 kg of food comes into contact with 6 dm<sup>2</sup> of packaging material.

The following substances subject to restriction under Regulation EU 10/2011 are used in the material:

Chemical name of the substances	CAS no.	Restrictions
Tetrafluoroethylene	0000116-14-3	SML = 0,05 mg/kg

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

#### Notes:

<sup>1)</sup> This declaration expires 3 years after its date of issue or in case of regulatory or compositional changes which require reevaluation. Please always contact Vink Plast' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.

<sup>2)</sup> Regulation (EC) no. 1935/2004 of the European Parliament and 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.

Finished food contact articles shall be manufactured such that the surface skin(s) of semifinished product is (are) taken away.

In accordance to GMP the food contact articles shall be thoroughly cleaned prior their first contact with food.


It is the responsibility of the buyer to assure traceability of the material during any further downstream use up to and including the finished machined part as well as the equipment in which it is assembled.

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