

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

Date of issue: July 2021 ¹⁾

Vink Plast ApS hereby declare that:

Vivak® Clear 099 FCM/ Vivak® Eco Clear 099 FCM (PETG) sheets and finished parts machined from these products by Vink Plast ApS ²⁾:

comply with:

- the requirements of EU regulation 1935/2004/EU
- Good manufacturing practice (GMP), EU 2023/2006 which are considered appropriate for plastic raw materials as required by Regulations.
- According to Article 19, regulation (EC) 10/2011 and amendment to date ((EU) 2020/1245 on plastic materials and articles intended to come into contact with food..
- This includes the procedures to cover traceability from the incoming starting materials to the outgoing food contact material.
- Declaration 681/2020/DK

Specific limits

The table below provides information on specific restrictions which must be observed according to Commission Regulation (EU) 10/2011.

Monomer	CAS	FCM	Restriction
Terephthalic acid	100-21-0	785	SML (T) 7.5 ppm as terephthalic acid
Ethylene glycol	107-21-1	227	SML (T) 30 ppm as ethylene glycol
Acetaldehyde	75-07-0	128	SML (T) 6 ppm as acetaldehyde

Use conditions

The above mentioned limits have met in exemplary investigations on sheets. Conditions for both overall migration and specific migration:

- Simulants: A, B and D2
- Duration: 10 days
- Temperature: 40 °C
- 4.3 dm²/liter simulant

The declaration of compliance is only valid for the temperature/time as described. It is the responsibility of the user of our products, who manufactures materials or articles intended for food contact or brings them into contact with food, to assure their compliance with limits and other provisions set by the applicable regulations.

Risk Assessment:

Risk assessment has been performed according to Article 19 regulation (EU) 10/2011 for the following use conditions for all food types (Simulants A, B and D2):

- Up to 70 °C for up to 2 hours.
- Up to 40 °C for up to 30 days.
- All storage times at refrigerated and frozen conditions.

It is the responsibility of the user of our products, who manufactures materials or articles intended for food contact or brings them into contact with food, to perform risk assessment according to article 19 of Commission Regulation (EU) 10/2011 for their own specific use conditions.

Annex II restriction:

None.

Dual Use additives:

None

Colorants:

None

USA

Based on the declaration of the raw materials supplier:

FDA-Regulation Title 21 Code of Federal Regulations Sec. 177.1315 "Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers."

Notes:

¹⁾ This declaration expires 5 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.


²⁾ 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.

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