



The polymer manufacturer:

Victrex Manufacturing Limited

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European Declaration of Compliance for VICTREX FG™ 121 and FG™ 221 glass fibre filled carbon black pigmented grade; Intended to be used in the manufacture of materials and articles intended to come into contact with food.

The information included in this document is valid from stated version date until this document is superseded.

Victrex Manufacturing Ltd declares that the VICTREX FG grades listed above are suitable to be used in the manufacture of materials and articles intended to come into contact with food:

The VICTREX FG 121 and FG 221 (glass fibre filled and carbon black pigmented grade) comply with the relevant requirements as laid down in:

- Framework Regulation (EC) 1935/2004, articles 3 and 17.
- Commission Regulation (EU) No 10/2011 relating to plastic materials and subsequent amendments up to 2019/37.
- Fabricated test specimens have been tested according to Commission Regulation (EU) No 10/2011.
- VICTREX PEEK polymer has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 articles 4, 5, 6 and 7.

The polymer contains monomers which are regulated with a specific migration limit (SML).



Table1. Substances with SML's

Monomers/additives	CAS	REF	LIMIT
4,4' DIFLUOROBENZOPHENONE	345-92-6	15820	0.05 mg/kg
1,4-DIHYDROXYBENZENE	123-31-9	15940	0.6 mg/kg

Migration tests on a number of VICTREX PEEK polymer grades have been performed according to Commission Regulation No 10/2011 on specially fabricated test specimens by an independent laboratory showed that under the following conditions the overall migration limits and specific migration limits were not exceeded.

Table 2.

Simulant	Time(s) / Temperature(s)
20% v/v aqueous ethanol	4 hours reflux repeat use
3% w/v aqueous acetic acid	4 hours reflux repeat use
Fat simulant	2 hours at 225°C repeat use

The polymer also contains substances other than monomers listed which are regulated with a specific migration limit (SML) in Commission Regulation (EU) No 10/2011 and amendments and also substances listed in Commission Regulation (EC) No 1333/2008 defined as dual additive, but which are not expected to change the properties of food as specified in Commission Regulation (EU) No 1935/2004.

The identity of these substances can only be disclosed for testing purposes under a signed non-disclosure agreement.

The suppliers of the carbon black used in the manufacture of VICTREX FG 121 and FG 221 have provided documentation confirming that it meets the purity requirements of the Commission Regulation (EU) No 10/2011 for carbon black CAS No 1333-86-4 Ref 42080.



Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limit according to Annex II of Commission European Regulation (EU) No 10/2011:

Aluminium 1 mg/kg, Barium 1mg/kg, Cobalt 0.05mg/kg, Copper 5mg/kg, Iron 48 mg/kg, Lithium 0.6mg/kg, Manganese 0.6mg/kg, Nickel 0.02mg/kg and Zinc 5mg/kg. Unfilled VICTREX PEEK polymer grades do not contain these substances at levels that exceed the specified limits on the basis of analytical tests.

Traceability of the product is ensured according to Commission Regulation (EC) No. 1935/2004.

Compliance with the overall migration limits and specific migration limits of the Commission Regulation (EU) No 10/2011 and subsequent amendments can only be demonstrated by tests carried out on the final article.

Signed

Date: 7th February 2019

Dr John Grasmeder
Chief Scientist