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Safety assessment of the substance chopped carbon fibres, from carbonised polyacrylonitrile, for use in food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of chopped carbon fibres, from carbonised polyacrylonitrile, as food contact material (FCM) substance No 1086, which is intended to be used as a filler for polyether ether ketone (PEEK) polymer at up to 40% w/w. The plastic is intended for repeated use in contact with all types of foods under all conditions of use. The chopped carbon fibres have a length of [REDACTED] and a diameter of [REDACTED], with no fragments lower than [REDACTED] in any dimension. They do not include a fraction of particles at the nanoscale and are fully embedded in the PEEK matrix, and therefore the fibres and any fragments are not expected to migrate. Based on the results of a battery of three genotoxicity tests, the Panel concluded that the substance does not raise a concern for genotoxicity. Therefore, the CEP Panel concluded that the substance chopped carbon fibres, from carbonised polyacrylonitrile, with a minimum carbon content of 95% (at sizes not at the nanoscale) does not raise a safety concern for the consumer if the substance is used as a filler at up to 40% w/w for PEEK plastic in contact with all food types and under all conditions of use.

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Keywords: chopped carbon fibres, from carbonised polyacrylonitrile, FCM substance No. 1086, filler, polyether ether ketone (PEEK), food contact materials, safety assessment, evaluation

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Waiver: R. Franz declared that Fraunhofer institute at which he was employed provides advisory services to private business operators active in the sector on food contact materials. In line with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, a waiver was granted to R. Franz regarding his participation to the EFSA's Working Group on Food Contact Materials (FCM WG) in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, the involvement of R. Franz is authorised as member in the FCM WG, allowing him to take part in the discussions and in the drafting phase of the scientific output, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the working group.

Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The following information has been provided under confidentiality and it is redacted awaiting the decision of the Commission: details on the manufacturing process, fibre size, impurities, thermal decomposition temperature, plastic formulation, genotoxicity studies.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

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† Deceased.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004¹ of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States' competent authorities which transmit the applications to the European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the French Competent Authority (Ministère de l'Économie, des Finances et de la Relance), requesting the evaluation of the substance chopped carbon fibre, with the FCM substance No 1086. The dossier was submitted on behalf of Victrex plc.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of their application for the authorisation of chopped carbon fibre to be used in plastic FCM.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 13 July 2021 (see '[Documentation provided to EFSA](#)').

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of substance/FCMs
- Physical and chemical properties
- Intended use
- Existing authorisation(s)
- Migration and residual content of substances from the host polymer

Toxicological data

- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian cell micronucleus test
- Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats

2.2. Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

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. OJ L 338, 13.11.2004, p. 4-17.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently there are three tiers with different thresholds triggering the need for more toxicological information as follows:

- a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
- b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
- c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee, in particular the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA, 2021).

3. Assessment

According to the applicant, the substance chopped carbon fibre, renamed 'chopped carbon fibres, from carbonised polyacrylonitrile' by the Panel, is used as a filling and reinforcement material at up to 40% w/w for polyether ether ketone (PEEK) plastic. The finished polymer is intended to be used in contact with all food types and under all conditions of repeated use.

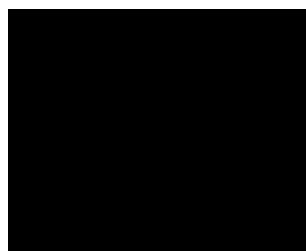
The substance has not been evaluated in the past by the SCF or EFSA.

The fibres may be sized before addition to PEEK to improve the handling of the fibres prior to the addition to the end use polymer. The sizing agent has no function in the final plastic. The Panel noted that it is a polymer production aid as defined in Article 3(8) and subject to derogation from being listed in the Union list as provided for by Article 6(1) of Regulation (EU) 10/2011. Therefore, the sizing agent is not subject to this opinion. Its safety needs to be assessed in accordance with internationally recognised scientific principles on risk assessment by the user in line with Article 19 of Regulation (EU) 10/2011.

3.1. Non-toxicological data

3.1.1. Identity of the substance²

Chemical structure of chopped carbon fibres, from carbonised polyacrylonitrile:



According to the applicant, the chopped carbon fibres, from carbonised polyacrylonitrile, are manufactured from continuous polyacrylonitrile (PAN) fibres converted to carbon fibres at [REDACTED]

The minimum carbon content is 95%.

They are part of the polymer.

² Technical dossier/section 1; Appendix B-Technical dossier/Annexes 2-4.

3.1.2. Physical and chemical properties³

Chopped carbon fibres are insoluble and chemically inert. The fibres including the sizing are thermally stable up to [REDACTED] which is above the manufacturing conditions of PEEK (up to 375°C).

The chopped carbon fibres have a length of [REDACTED] and a diameter of [REDACTED] (it is a high-aspect ratio material). The particle size was analysed by laser diffraction and electron microscopy and no fragments lower than [REDACTED] in any dimension were found. Cross-sections of PEEK plaques with chopped carbon fibres were also analysed by electron microscopy, which confirmed that the chopped carbon fibres are not in the nanoscale. The obtained images showed that the fibres are fully embedded in the PEEK matrix, and therefore the fibres and any fragments are not expected to migrate (Stoermer et al., 2017).

3.1.3. Migration data⁴

The overall migration from PEEK containing 40% w/w chopped carbon fibres into 3% acetic acid, 10% ethanol and olive oil was not significantly different from PEEK without the fibres.

For specific migration of residual monomers from the manufacture of PEEK, the applicant has tested PEEK filled with sized chopped carbon fibres. Samples were extracted twice for 24 h under reflux with acetonitrile for the analysis of [REDACTED]

[REDACTED], and with 1% acetic acid (containing also 1% potassium iodide as a stabiliser) for the analysis of [REDACTED]. The maximum potential migration was calculated using the results from the extractions. All measured substances are listed in Regulation (EU) No 10/2011 and their migrations were well below their respective specific migration limits (SMLs).

Volatiles from chopped carbon fibres after thermal desorption were analysed by GC-MS, but were not detected in the polar and non-polar extracts of the chopped carbon fibres.

3.2. Toxicological data

3.2.1. Genotoxicity⁵

3.2.1.1. Bacterial reverse mutation test

The test substance [REDACTED] (milled carbon fibre, purity 99.95%) as a surrogate for the chopped carbon fibres, was tested in a bacterial reverse mutation assay (Ames test) performed according to OECD TG 471 (OECD, 1997a) and following Good Laboratory Practice (GLP). The Panel considered this test substance as a suitable surrogate.

[REDACTED]

The Panel concluded that the test substance did not induce gene mutations under the conditions employed in the study.

3.2.1.2. Mammalian cell gene mutation test

The test substance [REDACTED] (milled carbon fibre, purity 99.95%) as a surrogate for the chopped carbon fibres, was tested in gene mutation assay at the thymidine-kinase (TK) locus in the mouse lymphoma L5178Y cell line following the OECD TG 476 (OECD, 1997b) and GLP. The Panel considered this test substance as a suitable surrogate.

³ Technical dossier/section 2; Appendix B-Technical dossier/Annexes 3-5.

⁴ Technical dossier/sections 5&6; Appendix B-Technical dossier/Annexes 6-15.

⁵ Technical dossier/section 8.1; Appendix B-Technical dossier/Annex 16 (1-3).

[REDACTED]

The Panel concluded that the test substance did not induce gene mutations under the conditions employed in this study.

3.2.1.3. *In vitro* mammalian cell micronucleus assay

The test substance [REDACTED] (chopped carbon fibre, purity > 95%) was tested in an *in vitro* micronucleus assay carried out according to OECD Draft Guideline 487 (OECD, 2016) and following GLP. [REDACTED]

[REDACTED]

The Panel concluded that, under the conditions employed in this study, the extracts of the test substance did not induce an increase in the frequency of MNBNs in cultured human peripheral blood lymphocytes.

3.2.2. General toxicity⁶

An acute toxicity study and a combined repeated dose toxicity study with a reproduction/developmental toxicity screening test in rats were provided by the applicant. The results of these studies are not reported in this opinion given that, based on the low migration, toxicological studies other than genotoxicity studies are not required (EFSA Note for Guidance, 2017). However, the Panel noted that there were no indications of toxicity from these studies.

3.2.3. Concluding remarks on toxicity

The genotoxicity studies were carried out with extracts of chopped carbon fibres or with milled carbon fibres (considered as a suitable surrogate). The milled carbon fibres were tested in two *in vitro* genotoxicity tests (Ames test, mouse lymphoma assay) with and without metabolic activation up to the limit concentrations. In the bacterial gene mutation assay, no revertants were detected at concentrations up to 5,000 µg/plate. In the mouse lymphoma assay, the milled carbon fibres were not mutagenic up to 5,000 µg/mL. The extracts of the chopped carbon fibres were tested with the micronucleus test in human peripheral lymphocytes. No increase of micronucleated cells was observed in cultures treated with DMSO (up to 2,000 µg/mL) or aqueous (up to 20,000 µg/mL) extracts of chopped carbon fibres.

Based on the results of a battery of three adequately performed genotoxicity tests, the Panel concluded that the chopped carbon fibres are not of concern for genotoxicity.

4. Conclusions

The CEP Panel concluded that the substance chopped carbon fibres, from carbonised polyacrylonitrile, with a minimum carbon content of 95% (at sizes not at the nanoscale), does not

⁶ Technical dossier/section 8.2; Appendix B-Technical dossier/Annex 16(4-5).

raise a safety concern for the consumer if used as a filler at up to 40% w/w for PEEK plastic in contact with all food types and under all conditions of use.

5. Remark

The Panel noted that due to the persistent character and the high aspect ratio of the chopped carbon fibres, there may be a concern for possible inhalation during manufacture and release at the end of life of the material.

6. Documentation as provided to EFSA

- 1) Technical dossier: Chopped carbon fibre. December 2020. Submitted by Intertek Chalon on behalf of Victrex plc.
- 2) Additional data. October 2021. Submitted by Intertek Chalon on behalf of Victrex plc.

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Abbreviations

bw	body weight
CAS	chemical abstracts service
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM	food contact materials
GC–MS	gas chromatography–mass spectrometry
GLP	Good Laboratory Practice
MNBN	micronucleated bi-nucleated cells
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PAN	polyacrylonitrile
PEEK	polyether ether ketone
SCF	Scientific Committee on Food
SML	specific migration limit
TK	thymidine–kinase