SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the substance, 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] CAS No 37486-69-4 for use in food contact materials

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety evaluation of the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] (CAS No 37486-69-4, FCM substance No 903), for use as polymer production aid (PPA) for manufacturing sintered and non-sintered (processed) fluoropolymers. Finished articles are intended to be used for single and repeated contact with all kinds of foodstuffs at all temperatures. Residual content of the substance was not detected in sintered or processed (non-sintered) articles at temperatures at or above 360°C and was detected in fluoropolymers processed (non-sintered) at 300°C from which total mass transfer was calculated to be 13 µg/kg food. Based on migration modelling under highly conservative assumptions, estimated migration of the substance present at the measured residual level in articles processed (non-sintered) at temperatures of 300°C, is in the range of 1 µg/kg. For repeated use applications, migration at each following use will be considerably lower. Based on negative results from three adequately performed in vitro genotoxicity tests, the Panel considered that the substance is non-genotoxic. The CEF Panel concluded that there is no safety concern for the consumer if the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] is only used as a polymer production aid in the polymerisation of fluoropolymers intended for:

A. repeated and single use materials and articles
   - when sintered or processed (non-sintered) at temperatures at or above 360°C for at least 10 minutes or at higher temperatures for equivalent shorter times,

B. repeated use materials and articles only
   - when processed (non-sintered) at temperatures from 300°C and up to 360°C for at least 10 minutes.

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**KEY WORDS**

2H-Perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]; CAS No 37486-69-4; FCM substance No 903; Food contact materials; Safety assessment; Evaluation.
SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food and according to the 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 foodstuffs, the CEF Panel received a request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany for safety evaluation of the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] following a corresponding application submitted on behalf of the company DYNEON GMBH, Germany.

The safety evaluation of 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] with the CAS No 37486-69-4 and the FCM substance No 903 was requested for use as polymer production aid (PPA) for manufacturing sintered and non-sintered (processed) fluoropolymers. Finished articles are intended to be used for single and repeated contact with all kinds of foodstuffs at all temperatures.

The substance consists of five C$_3$F$_6$O monomer units. The main impurities are oligomeric substances with four, six and seven monomer units.

Residual content of the substance was detected in fluoropolymers processed at 300°C while it was not detected in fluoropolymers sintered or processed typically at or above 360°C. Considering total mass transfer of the substance present at the measured residual level in fluoropolymers processed at 300°C and at the limit of detection in fluoropolymers sintered and processed typically at or above 360°C, worst case migration was calculated to be 13 µg/kg food and up to 3.4 µg/kg food respectively. Considering migration modelling under highly conservative assumptions, the estimated migration of the substance present at the measured residual level in fluoropolymers processed at 300°C and at the limit of detection in fluoropolymers sintered and processed typically at or above 360°C, was calculated to be in the range of 1 µg/kg food and of 0.1 µg/kg food respectively. For repeated use applications, migration at each following use will be considerably lower.

Based on negative results from three in vitro genotoxicity tests, the Panel considered that the substance is non-genotoxic.

It is noted that some perfluorinated compounds may show a high potential for accumulation in man. However the proposed conditions of use would lead to a negligible migration. Based on very conservative assumptions, an exposure of less than 1 µg/person/day could be estimated. Under these conditions the Panel has no indication for safety concern for this substance.

The EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids concluded that there is no safety concern for the consumer if the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] is only used as a polymer production aid in the polymerisation of fluoropolymers intended for:

A. repeated and single use materials and articles
   - when sintered or processed (non-sintered) at temperatures at or above 360°C for at least 10 minutes or at higher temperatures for equivalent shorter times,

B. repeated use materials and articles only
   - when processed (non-sintered) at temperatures from 300°C and up to 360°C for at least 10 minutes.

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2H-Perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]

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BACKGROUND AS PROVIDED BY THE LEGISLATION

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA’s opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the 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 food5.

According to this procedure the industry submits applications to the Member States competent Authorities which transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the SCF guidelines for the “presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation” (EC, 2001).

In this case, EFSA received an application from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requesting the evaluation of the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether].

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

The EFSA is required to carry out risk assessment on the risks originating from the migration into food of the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] for use as polymer production aid (PPA) for manufacturing sintered and non-sintered (processed) fluoropolymers and to deliver a scientific opinion 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.

ASSessment

1. Introduction

The European Food Safety Authority was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, to evaluate the safety of 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] with a CAS No 37486-69-4 and a FCM substance No 903. The request has been registered in the EFSA’s register of received questions under the number EFSA-Q-2011-00966. The dossier was submitted on behalf of the applicant, DYNEON GMBH, Germany.

2. General information

According to the applicant, the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] (TFEE₂₃) is intended to be used as a polymer production aid (PPA) in the manufacture of various fluoropolymers. Most articles made from fluoropolymers and fluorothermoplastics are sintered typically at 360°C for approximately 10 minutes. Non-sintered articles are processed at temperatures higher than the melting point of the respective material at around 300°C for partially fluorinated and typically around 360°C for fully fluorinated polymers for approximately 10 minutes. Applications are typically for contact with all food types at all temperatures and for repeated use. Single use is also foreseen.

The sintered fluoropolymers are used to produce non-stick coatings and kitchen utensils like pans and other articles that come into contact with foodstuffs for repeated use. The thickness of such coatings ranges between 30-95 µm. Furthermore, solid non-sintered fluoropolymers are used to produce items like films, bags, tubing, gaskets, seals, pipes, conveyor belts, liners, plates and sheets. Many of these applications are typically repeated use articles. Applications like films, bags, plates and sheets are single use articles. Films may be used to wrap meat, cheese or vegetables or for food heating in the microwave; bags may be used for storing food in the deep freezer; sheets may be used in contact with butter, cheese and milk.

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

3. Data available in the dossier used for this evaluation

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (EC, 2001).

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation
- Data on residual content of the substance
- Data on worst-case migration

Toxicity data:
- Bacterial gene mutation test
- In vitro mammalian cell gene mutation test
- In vitro mammalian chromosome aberration test
4. Evaluation

4.1. Non-toxicological data

Chemical formulae: \( \text{C}_{17}\text{H}_{35}\text{O}_5 \)

Chemical structure:

![Chemical structure diagram]

The substance, 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] (TFEE₅), has a molecular weight of 950.1 Da. It has a log \( P_{ow} \) of 9.4 and dissolves poorly in water. Boiling point at atmospheric pressure is about 225°C.

The substance consists of five \( \text{C}_3\text{F}_6\text{O} \) monomer units (TFEE₅). Purity is 90% and main impurities are structurally related. These are TFEE₄ (≤0.5%), TFEE₆ (≤10%) and TFEE₇ (≤0.5%) with \( n = 4, 6 \) and 7, respectively.

Decomposition of the substance starting from 370°C is indicated by a differential scanning calorimetry (DSC) analysis. Due to the perfluorinated character of the substance, degradation products which may be formed at this temperature are expected to be volatile and removed from the polymer during this sintering/processing step. Therefore migration of degradation products into the food is not expected.

Specific migration of the substance was not tested. Instead, worst case and modelled migrations were calculated based on the residual content determined in fluoropolymers after sintering and processing (non-sintered).

The residual content, expressed as the sum of TFEE₅ and TFEE₆, was not detected at a detection limit of 0.1 mg/kg and 0.05 mg/kg after sintering or processing at 360°C for 10 minutes respectively. After processing at 300°C for approximately 10 minutes, residual content was 0.4 mg/kg polymer.

Considering total mass transfer of the substance present at the measured residual level in fluoropolymers processed at 300°C and at the limit of detection in fluoropolymers sintered and processed typically at or above 360°C, worst case migration was calculated to be 13 μg/kg food and up to 3.4 μg/kg food respectively. Due to the intrinsic low diffusion properties of fluoropolymers, the large molecular size of the substance and based on generally recognised migration modelling (EC, 2010; Piringer and Baner, 2008), it can be anticipated that total mass transfer does not occur for the intended uses. Therefore, conservative migration modelling was applied to better estimate migration of the substance for two potential applications: from a fluoropolymer sheet of 200 μm thickness in contact with fatty food for 1 month at room temperature and for 2 hours at 70°C. Conservative migration modelling was achieved by assuming for the fluoropolymer the same migration behaviour as for low density polyethylene (LDPE) which is generally recognised as the polymer with the highest diffusion properties amongst the conventional food contact polymers. Modelled migration of the substance present at the limit of detection from sintered or processed (non-sintered) articles at temperatures at or above 360°C was in the range of 0.1 μg/kg food. For processed (non-sintered) articles at temperatures from 300°C and up to 360°C, modelled migration was in the range of 1 μg/kg food. For repeated use applications, migration at each following use will be considerably lower.
4.2. Toxicological data

The substance was tested in three in vitro genotoxicity tests with and without metabolic activation. In the bacterial reversion mutation test using the *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and the *Escherichia coli* strain WP2uvrA, the substance did not induce gene mutations when tested up to 5000 µg/plate in the first experiment and up to 3333 µg/plate in the second experiment. In the mouse lymphoma assay, no mutations were induced when the substance was tested up to 100 µg/ml (limited by precipitation in the test media), and the substance did not induce chromosomal aberrations in human peripheral lymphocytes when tested up to 100 µg/ml. Based on the results of these three in vitro tests, the Panel considered that the substance is non-genotoxic.

It is noted that some perfluorinated compounds may show a high potential for accumulation in man. However the proposed conditions of use would lead to a negligible migration. Based on very conservative assumptions, an exposure of less than 1 µg/person/day could be estimated. Under these conditions the Panel has no indication for safety concern for this substance.

CONCLUSIONS

The EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids concluded that there is no safety concern for the consumer if the substance 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] is only used as a polymer production aid in the polymerisation of fluoropolymers intended for:

A. repeated and single use materials and articles
   - when sintered or processed (non-sintered) at temperatures at or above 360°C for at least 10 minutes or at higher temperatures for equivalent shorter times,

B. repeated use materials and articles only
   - when processed (non-sintered) at temperatures from 300°C and up to 360°C for at least 10 minutes.

REMARK TO THE COMMISSION

The substance is a polyfluoro compound, which are a class of persistent, widespread environmental pollutants.

DOCUMENTATION PROVIDED TO EFSA


REFERENCES


EC (European Commission), (2001). Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior its authorisation; http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf.

**GLOSSARY AND ABBREVIATIONS**

<table>
<thead>
<tr>
<th><strong>Overall migration</strong></th>
<th>The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific migration</strong></td>
<td>The amount of a specific substance released from a food contact material or article into food or food stimulant</td>
</tr>
<tr>
<td><strong>CAS</strong></td>
<td>Chemical abstracts service</td>
</tr>
<tr>
<td><strong>CEF</strong></td>
<td>Scientific Panel on food contact materials, enzymes, flavourings and processing aids</td>
</tr>
<tr>
<td><strong>Da</strong></td>
<td>Dalton</td>
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<tr>
<td><strong>EC</strong></td>
<td>European Commission</td>
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<tr>
<td><strong>EFSA</strong></td>
<td>European food safety authority</td>
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<tr>
<td><strong>FCM</strong></td>
<td>Food Contact Material(s)</td>
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<tr>
<td><strong>Po/w</strong></td>
<td>Octanol/water partition coefficient</td>
</tr>
<tr>
<td><strong>PPA</strong></td>
<td>Polymer production aid</td>
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<tr>
<td><strong>TFEE5</strong></td>
<td>2H-Perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]</td>
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