baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

2H-Tricosafluoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane

(TFEE-5)

CAS 37486-69-4

Evaluating Member State(s): Germany

Dated: November 2020

Template Version 2.1
March 2015

Evaluating Member State Competent Authority

BAuA
Federal Institute for Occupational Safety and Health
Division 5 - Federal Office for Chemicals
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund, Germany

Year of evaluation in CoRAP: 2017

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

The Substace, 2H-Tricosafluoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane (hereafter called TFEE-5) was originally selected for substance evaluation in order to clarify concerns about suspected PBT/vPvB and exposure of the environment. During the evaluation, global warming potential was identified as an additional concern.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

There are no other processes known.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	x
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Not applicable.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

4.1.3. Restriction

TFEE-5 is a member of the substance group of per-and polyfluoroalkyl substances (PFAS). PFAS are highly persistent in the environment (or degrade to highly persistent degradation

products) and have the potential to contaminate groundwater, surface water and soil. The presence of the substances in the environment is practically irreversible and poses an unacceptable risk to the environment and humans. A broad restriction of PFAS (including TFEE-5) will be the most appropriate risk management measure to minimize concentrations of these persistent substances in the environment.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Not applicable, see section 4.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment by the evaluating Member State. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Table 2

Follow-up		
Follow-up action	**Date for intention**	**Actor**
Annex XV dossier for restriction (broad PFAS restriction)	2021	Germany, the Netherlands, Norway, Sweden and Denmark

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

The Substance, 2H-Tricosafluoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane (hereafter called TFEE-5) was originally selected for substance evaluation in order to clarify concerns about suspected PBT/vPvB and exposure of the environment. During the evaluation, global warming potential was identified as an additional concern.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Persistence	TFEE-5 is not readily biodegradable and regarded as highly persistent in the environment. Concern substantiated.
Bioaccumulation	TFEE-5 does not meet the screening criterion for B/vB according to the recalculation of the log K_{ow} by the registrant and the eMSCA. However, there is for instance a contradictory K_{ow} value given in the EFSA report as well as a higher calculated K_{ow} Concern not clarified.
Environmental toxicity	It is not possible to conclude whether TFEE-5 does fulfil the criteria for toxicity of REACH Annex XIII based on available information. The studies provided by the registrant are not acceptable according to the eMSCA. TFEE-5 and/or its impurities may be toxic to aquatic organisms. Concern not clarified.
Exposure of environment	TFEE-5 can be released widely dispersively into the environment with non-sintered fluoropolymers that contain TFEE-5 in traces. During the processing of fluoropolymers, TFEE-5 may be released to the atmosphere. However, the expected amount of TFEE-5 being released to the environment seems to be low based on information provided by the registrant. No further action.
Global warming potential	No information on the atmospheric lifetime and the global warming potential are available for TFEE-5 and its impurities. However, due to the structural similarity of TFEE-5 and its impurities to the perfluoropolyethers (PFPEs) investigated, these substances may show a similar behaviour in the atmosphere resulting in a long atmospheric half-life and thereby potentially contributing to global warming. However, based on the exposure information and effective risk management measures it is considered unlikely that TFEE-5 reaches the atmosphere. No further action.

7.2. Procedure

This substance evaluation was targeted on the assessment of endpoints with relevance to the environment; human health endpoints have not been evaluated. The registration data were the basis of the assessment.

Based on the available data in the registration dossier the eMSCA issued a draft decision with the following information requirements:

1. Bioaccumulation in aquatic species; test method: Bioaccumulation in fish, aqueous exposure, OECD 305.

2. Long-term toxicity testing on aquatic invertebrates; test method: Daphnia magna reproduction test, EU C.20./OECD 211. The toxicity testing can be waived if the substance does not fulfil the B criterion according to REACH Annex XIII or fulfils the vB criterion according to REACH Annex XIII.

3. Long-term toxicity testing on fish; test method: Fish, early-life stage (FELS) toxicity test, OECD 210. The toxicity testing can be waived if the substance does not fulfil the B criterion according to REACH Annex XIII or fulfils the vB criterion according to REACH Annex XIII or fulfils the T-criterion tested under 2.

In July 2017, a meeting with the registrant took place during which the registrant provided further data on uses.

During commenting on the draft decision, the registrant corrected erroneous data on the water solubility and the log K_{ow} contained in the registration dossier. The recalculation is regarded as plausible by the eMSCA. With this new K_{ow} the screening criterion is no longer met for aquatic bioaccumulation. On the other hand, this K_{ow} is contradictory to the published EFSA opinion for TFEE-5 which reports a value of log K_{ow} = 9.4 (EFSA, 2012). This value is in the same range as a calculated K_{ow} based on COSMOtherm which has been conducted by the eMSCA. However, it is not clear on which data basis the log K_{ow} given in the EFSA report has been derived. Therefore, the eMSCA considers the data basis inconclusive or at least ambiguous with regard to the bioaccumulation screening.

Though the PBT concern is not clarified the eMSCA refrains from further data request due to proportionality. The expected amount of TFEE-5 being released to the environment seems to be low based on information provided by the registrant. As a consequence, the request for a bioaccumulation study according to OECD 305 as well as requests for information of aquatic toxicity were withdrawn and the decision making process was terminated by the eMSCA.

7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	2H-Tricosafluoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane
EC number:	confidential
CAS number:	37486-69-4
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	confidential
Molecular weight range:	confidential
Synonyms:	TFEE-5;

	Polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane

Type of substance ☒ Mono-constituent

Structural formula:

Information on the structure and composition of TFEE-5 is contained in a confidential annex to the evaluation report.

7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Clear colourless liquid at 22.0 °C (visual inspection)
Melting/freezing point	Below −60 °C (Measured by differential scanning calorimetry according OECD Guideline 102 / EU Method A.1)
Boiling point	222 – 225 °C (Distillation method according to OECD 103 and EU A.2 and dynamic method according to OECD 104 and EU A.4)
Vapour pressure	C. 2 Pa at 20 °C (Dynamic method according to OECD 104 / EU A.4)
Density	1.80 $g.cm^{-3}$ at 20 °C (Pycnometer method according to OECD 109 / EU A.3)
Water solubility	0.3 $mg.L^{-1}$ at 25 °C and pH = 7 (Flask method according to EU A.6 and OECD 105)
Partition coefficient n-octanol/water (Log K_{ow})	2.8 at 25 °C (Slow-Stirring method according to OECD 123) 9.4 from EFSA report > 10 (COSMOtherm estimate) 12.21 (KowWin estimate)
Partition coefficient n-octanol/air (Log K_{oA})	9.577 estimated by KOAWIN v1.10 using Log Kow: 12.21 (KowWin estimated) and 10.5 atm-m3/mole (HenryWin estimated) −0.03 estimated by KOAWIN v1.10 (using Log Kow: 2.60 (user entered) and 10.5 atm-m3/mole (HenryWin estimated) 6.77 estimated by KOAWIN v1.10 using Log Kow: 9.4 (user entered) and 10.5 atm-m3/mole (HenryWin estimated)
Surface tension	71.2 $mN{\cdot}m^{-1}$ at 20 °C (Ring method according to EU A.5 and OECD 115)
Viscosity	8.46 $Pa{\cdot}s^{-1}$ at 20 °C (4.77 $Pa.s^{-1}$ at 40 °C, capillary viscometer method according to OECD 114)
Granulometry	Data waiver
Dissociation constant	Data waiver

Water solubility

The registrants stated in their comments to the draft decision that during the substance evaluation a review of available data on environmental fate was performed. Especially, data about waste water discharge and accompanied physicochemical data were reviewed. Thereby it was found, that the analytical report provided contradictory values in the different sections. While the summary section states a water solubility of 0.3 µg/L, the review of the analytical data section suggests a solubility of 0.3 mg/L.

Based on the analytical data and revision provided by the registrant, a water solubility of 0.3 mg/L at 25 °C is considered as plausible by the eMSCA.

Partition coefficient n-octanol/water (Log K_{ow})

As correctly described by the registrant, a few calculation errors resulted in a Log K_{ow} of 6.4. Firstly, the correct calibration function was not used for the experimental peak areas to determine the concentration of TFEE-5 in the hexane extract. Secondly, the mass concentration of TFEE-5 in the hexane extract with the unit µg/g was converted to the unit µg/l, while the value was not adopted accordingly. Based on the analytical data and the correction of the two errors, a K_{ow} of 2.6 was calculated by the registrant.

Unfortunately, the density of hexane was not considered for the calculation of Log K_{ow} = 2.6. When the density is taken into account, a Log K_{ow} of 2.8 is obtained.

Therefore, the registrant's recalculations regarding the water solubility and the log P value of TFEE-5 are plausible.

Nevertheless, this K_{ow} is contradictory to the published opinion of the European Food Safety Authority (EFSA) for TFEE-5 which reports a log K_{ow} of 9.4 (EFSA 2012). This value is in the same range as a calculated K_{ow} based on COSMOtherm which has been conducted by the eMSCA. However, it is not clear on which data basis the log K_{ow} given in the EFSA report has been derived. Therefore, the eMSCA considers the data basis inconclusive or at least ambiguous with regard to the bioaccumulation screening.

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☒ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

Uses in the registration dossier are claimed confidential and thus not available on ECHA's website (see confidential annex for further details). EFSA states in its scientific opinion that TFEE-5 is used as polymer production aid for manufacturing sintered (produced at 360 °C) and non-sintered (produced around 300 °C) fluoropolymers, so called "processed fluoropolymers". Finished articles are intended to be used for single and repeated contact with foodstuffs over a wide temperature window (EFSA, 2012).

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 articles are typically intended for

repeated use. 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 (EFSA, 2012).

Table 7

USES	
	Use(s)
Uses as intermediate	ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the types of manufacture using this substance.
Formulation	ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the types of manufacture using this substance.
Uses at industrial sites	Use as industrial processing aid for fluoropolymer production
Uses by professional workers	ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the types of manufacture using this substance.
Consumer Uses	ECHA has no public registered data indicating whether or in which chemical products the substance might be used.
Article service life	May occur in trace levels in the final polymer-based articles.

7.6. Classification and Labelling

There is no harmonised classification available for TFEE-5 in Annex VI of CLP.

No self-classification is given by the registrant and no further hazard classes are notified in the C&L inventory.

7.7. Environmental fate properties

TFEE-5 is a poorly soluble substance with a log K_{ow} of 2.8. TFEE-5 and its impurities are not readily biodegradable and the substance is considered highly persistent in the environment. No simulation study for TFEE-5 or its impurities is available.

7.7.1. Degradation

Table 8

Method	Result	Remark	Reference
Test type: ready biodegradability sewage, domestic, non-adapted	% Degradation of test substance: 3% after 28 days (CO_2 evolution)	1 (reliable without restriction) key study experimental result Test material: TFEE-5	Registration dossier

OECD Guideline 301 B (Ready Biodegradability: CO_2 Evolution Test)			

In the test for ready biodegradability according to OECD 301 B, no degradation of TFEE-5 was observed under test conditions. All validity criteria are fulfilled.

No further data on degradation (biotic and abiotic) is provided by the registrant.

Based on BIOWIN v4.10 the substance is considered to be potentially persistent or very persistent:

BIOWIN 1: –6.4034 (does not biodegrade fast)

BIOWIN 2: 0 (does not biodegrade fast)

BIOWIN 3: –4.1428 (recalcitrant)

BIOWIN 4: –0.7526 (recalcitrant)

BIOWIN 5: –0.3482 (not readily degradable)

BIOWIN 6: 0 (not readily degradable)

BIOWIN 7: –3.9583 (does not biodegrade fast)

Ready biodegradability prediction: no

According to REACH guidance document R.11, a substance is potentially persistent or very persistent if the following screening criteria are fulfilled: BIOWIN 2 value < 0.5 and BIOWIN 3 value < 2.25 or BIOWIN 6 value < 0.5 and BIOWIN 3 value < 2.25. The values for TFEE-5 are well below these screening criteria.

However, there are some limitations for the predictions of perfluorinated compounds with BIOWIN. This is because the training data set is incompletely implemented for perfluorinated carbon chains. Nevertheless, as it is considered that the perfluorinated carbon chain is expected to be very stable but not properly included in the BIOWIN model, it can be concluded that the persistence of perfluorinated substances will be underestimated by the BIOWIN predictions.

Perfluoropolyethers constitute a group of structurally similar substances which share the occurrence of multiple perfluoroether functionalities (Table 9). They show nearly no potential for degradation, as described by Wang et al. (2015). The authors concluded that under environmentally relevant conditions perfluoroether chains are similarly resistant to abiotic (photolysis, reactions with OH radicals, and hydrolysis) and biotic degradation as the perfluoroalkyl chains.

The stability of organic fluorinated compounds has been described in detail by Siegemund et al. (Siegemund et al., 2000): "When all valences of a carbon chain are satisfied by fluorine, the zig-zag-shaped carbon skeleton is twisted out of its plane in the form of a helix. This situation allows the electronegative fluorine substituents to envelope the carbon skeleton completely and shield it from chemical attack. Several other properties of the carbon-fluorine bond contribute to the fact that highly fluorinated alkanes are one of the most stable organic compounds. These include polarisability and high bond energies, which increase with increasing substitution by fluorine. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds. Properties that are exploited commercially include high thermal and chemical stability".

Thus, the eMSCA concludes that TFEE-5 fulfils the P and the vP criteria of REACH Annex XIII.

Table 9

DEGRADATION OF PERFLUOROETHER CARBOXYLIC ACIDS (ACCORDING TO THE REGISTRATION DOSSIERS)			
Structure	**CAS**	**Hydrolysis**	**Biodegradation**
$CF_3OC_3F_6OCHFCF_2COO^-$ (ADONA)	480-310-4	Hydrolytically stable	301B: not readily biodegradable
$C_3F_7OCF(CF_3)COO^-$ (Dimer acid of hexafluoropropyleneoxide; 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, HFPO-DA)	62037-80-3 (ammonium salt of HFPO-DA)	Hydrolytically stable	301B: not readily biodegradable 302C: not inherently biodegradable* Based on the lack of any primary degradation in the screening tests available on biodegradation, predictions on biodegradation by BIOWIN, and the very high degree of fluorination it is concluded that the biodegradation of the substance in the environment is likely to be very slow or negligible. The MSC support document concludes that the substance is very highly persistent under environmental conditions. (ECHA, 2019)
$C_2F_5OC_2F_4OCF_2COO^-$ (EEA)	908020-52-0	Hydrolytically stable	301C: not readily biodegradable

* The Member State Committee (MSC) for the SVHC identification of HFPO-DA according to Art. 57f) concluded that '[i]ts high persistency implies that HFPO-DA will remain in the environment for much longer times than most other substances that are identified as exhibiting P or vP properties'.[2]

7.7.2. Atmospheric lifetime and global warming potential

No information on the atmospheric lifetime and the global warming potential are available for TFEE-5 and its impurities.

In the literature a study assessing the atmospheric lifetime of structurally related perfluoropolyethers (PFPEs) is available (Young et al., 2006). In the study a commercial mixture has been used, composed mainly of a mixture of $CF_3OCF(CF_3)CF_2OCF_2\text{-}OCF_3$, with smaller amounts of $CF_3OCF(CF_3)CF_2OCF_2OCF_2\text{-}OCF_3$ and longer-chain analogues. By means of an atmospheric chamber system it is shown that the lifetime of PFPEs with respect to reaction with OH radicals is greater than 46 years. How much greater is impossible to assess. Very likely photolysis in the upper atmosphere plays the dominant role in atmospheric degradation. As the lifetime based on the photolysis in the upper atmosphere is estimated to be at least 800 years, moreover a global warming potential was identified (9000 relative to CO_2 and 1.95 relative to CFC-11 , Young et al., 2006). Because of the structural similarity of TFEE-5 and its impurities to the PFPEs studied by Young et al (2006), these substances may show a similar behaviour in the atmosphere resulting in a long atmospheric halftime and may have a global warming potential.

However, based on the exposure information and effective risk management measures in place at the site of use, release into the atmosphere is considered as unlikely during fluoropolymer processing.

[2] MSC Support document on the identification of HFPO-DA as SVHC based on Article 57f) adopted on 26 June 2019: https://echa.europa.eu/documents/10162/53fa6a5b-e95f-3128-ea9d-fa27f43b18bc

7.7.3. Environmental distribution

According to the registrant, TFEE-5 is removed from waste water efficiently, because the substance is hardly water soluble. The substance adsorbs onto activated carbon. Depending on the log K_{ow}, EPIsuite 4.1 provides a sludge adsorption of about 91% (log Kow = 9.4) or 1.17% (log Kow = 2.6), respectively. However, there are some limitations for the predictions of perfluorinated compounds with EPISuite. This is because the training data set is incompletely implemented for perfluorinated carbon chains. Modelling is very sensitive to key parameters like logKow, water solubility and the Henry`s Law constant. Therefore the correct estimation of these parameters is necessary for a reliable prediction of environmental distribution. According to the manufacturer, due to the high boiling point of 226 °C, TFEE-5 could be emitted into air only in process of drying the raw material.

7.7.4. Bioaccumulation

No experimental study regarding the bioaccumulation potential of TFEE-5 is available.

Based on the experimentally derived log K_{ow} of 2.6 TFEE-5 does not meet the screening criterion for B/vB. However, there is a contradictory K_{ow} value given in the EFSA report with a K_{ow} of 9.4 as well as calculated log K_{ow}> 10. Due to this range of different K_{ow} values K_{oA} values likewise vary considerably. The log K_{oA} based on the given K_{ow} value by the registrant does not indicate a potential for terrestrial bioaccumulation whereas the other values do. Therefore none of the physical-chemical data on partitioning are conclusive concerning bioaccumulation either in the aquatic or terrestrial compartment.

The registrant calculated the average maximum diameter ($D_{max\ ave}$) of TFEE-5 using the BCF base-line model v.02.09 within OASIS Catalogic v 5.11.17 and SPARTAN v 2.0. The modeled BCF value (not given) indicates a low bioaccumulation potential. However, the structure of TFEE-5 is not in the domain of the BCF base-line model v.02.09. Thus, the results are not reliable. Furthermore, the model is based on a log K_{ow} of 12.5 calculated by EPISuite.

The $D_{max\ ave}$ is predicted to be 1.81 nm (range, 1.43 - 2.41 nm) using Catalogic and in the range of 1.41 – 2.19 using SPARTAN v2.0. The registrant concludes that the $D_{max\ ave}$ is above 1.7 nm and therefore, TFEE-5 exists in stable conformation(s) that are too large to pass through biological membranes. ECHA Guidance (v. 3.0, 2017) states that a substance is possibly not B if the $D_{max\ ave}$ is above 1.7 nm, in combination with other data indicating limited uptake such as a chronic toxicity studies with mammals (≥ 90 days) which show no toxicity or toxicokinetics studies with mammals or birds. No chronic mammalian toxicity studies are available for TFEE-5. In an acute oral toxicokinetic screening study (Guideline: customized toxicokinetic screening protocol) with rats TFEE-5 was not taken up from the digestive tract after single dosage. The administered dose of TFEE-5 was recovered completely in the feces. The registrant concludes that TFEE-5 is also unlikely to pass gill membranes. Even though this study is an indication that the uptake of TFEE-5 might be low, it is not sufficient to conclude that TFEE-5 is not taken up in a bioaccumulation study with fish. As discussed in Section 7.8.1, there is no information available on the toxicity of TFEE-5 to fish but some toxic effects were observed in an acute Daphnia study which suggests that uptake is possible.

Conclusion

Experimental data on bioaccumulation is missing. An acute oral toxicokinetic screening study indicates low uptake. A kinetic half-life for this study is not given. The substance does not meet the screening criterion for B/vB according to the recalculation of the log K_{ow} by the registrant and the eMSCA. However, there is for instance a contradictory K_{ow} value given in the EFSA report as well as calculated K_{ow}. K_{oA} values likewise vary considerably.

Altogether none of these values are conclusive concerning bioaccumulation either in the aquatic or terrestrial compartment.

The concern is not clarified.

7.8. Environmental hazard assessment

Based on the results of the available GLP compliant acute limit test with *Daphnia magna* according to OECD 202 with 48 hours of exposure there is a concern that the substance is acutely toxic to aquatic invertebrates. However, the test was not performed according to the OECD guidance on aquatic toxicity testing of difficult substances (OECD 23, 2019) and is not conclusive since a higher toxicity was reported for test solutions with a lower concentration. Therefore, the results are not plausible and this test is not reliable.

No significant effects on yield or growth was observed for *Pseudokirchneriella Subcapitata* in the test according to OECD 201 with 72 hours of exposure. The test is regarded reliable with restrictions by the registrant as the test concentration was not maintained. Similar deficiencies as observed in the acute toxicity test to Daphnia were observed, e.g. test material preparation decrease below the LOD/LOQ after 24 hours.

The eMSCA considers that the registered substance is poorly water-soluble. The REACH regulation Annex VII section 9.1.2 column 2 concludes that "long-term aquatic toxicity study on *Daphnia* (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble". Currently, there is no long-term toxicity test with *Daphnia* available.

7.8.1. Aquatic compartment (including sediment)

Fish

No information on the short-term or long-term toxicity of TFEE-5 to fish is available and no experimental study is provided in the registration dossier.

Aquatic invertebrates

Table 10

EFFECTS ON AQUATIC INVERTEBRATES			
Method	**Result**	**Remark**	**Reference**
Daphnia magna freshwater static OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test)	EC_{50} (48 h): > 100 mg/L nominal, based on: mobility (No statistically significant immobilization or mortality was observed after 48 hours of exposure to 100% of the water soluble fraction, but to the lower concentrations)	Not reliable because the test was not performed according to the guidance experimental result Test material: TFEE-5	Registration Dossier (Test laboratory, 2010a)

The registrant provided a GLP compliant acute test with *D. magna* according to OECD 202 with 48 hours of exposure. The highest test concentration had a loading rate of 100 mg/L and was regarded as containing 100% of the water soluble fraction (WSF) of TFEE-5 after 25 hours of magnetic stirring. The registrant reports that the final solution was clear and colourless with a precipitate in the form of droplets. The solution was left to settle for 2 hours after which the water soluble fraction (WSF) was collected by siphoning from the middle. Three lower test concentration solutions were prepared by subsequent dilution of

the WSF in test medium to obtain additionally 0.1, 1 and 10% of the WSF as test concentrations. Within the test, analytical monitoring was just conducted in the 100% WSF treatment at the start and end of the test. The test concentrations could not be maintained. According to the registration dossier, the measured concentrations dropped from 0.175 mg/L to below the limit of detection (0.14 mg/L) during the 48 hours. As the test concentrations were not maintained during the 48 hours of exposure, the study is regarded as reliable with restrictions by the registrant.

No mortality was observed in the control. In the 0.1, 1, 10 and 100%-WSF treatments mortalities between 10% and 30% were observed. The registrant concluded that TFEE-5 is not acutely toxic to aquatic invertebrates and derived an EC_{50} of > 100 mg/L on the basis of the loading rate.

The eMSCA considers the provided test as not reliable. According to the OECD guidance document 23 (OECD 23, 2019), WAFs are prepared individually and not by serial dilution of a single stock WAF. Following cessation of mixing and a period of settling (to allow phase separation) the aqueous phase, i.e. the WAF, is drawn off for testing.

The eMSCA concludes that toxic effects were observed in each treatment of the acute study (10 – 30% mortality). Measured concentrations were already in the highest treatment concentration clearly below the loading rate with 0.1 mg/L (geometric mean, lowest concentration regarded as half the limit of detection). It is likely that impurities of TFEE-5 with a higher water solubility, may have a higher contribution in diluted WSF fractions. Thus, the acute toxicity test already indicates effects of TFEE-5 to aquatic invertebrates.

It is not plausible why the toxicity in lower test concentration is higher compared to the 100% WSF (100 mg/L).

Despite the fact that the registered substance is poorly water-soluble (with a water solubility of 0.3 mg/L which is below 1 mg/L) and the REACH regulation Annex VII section 9.1.2 column 2 concludes that "long-term aquatic toxicity study on daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble", there is no long-term toxicity test with *Daphnia* available.

Algae and aquatic plants

Table 11

EFFECTS ON ALGAE			
Method	**Result**	**Remark**	**Reference**
Peseudokirchneriella subcapitata Limit-test (only the highest test concentration was prepared according to OECD Guidance No.23) Freshwater, static OECD Guideline 201 (Alga, Growth Inhibition Test)	E_rC_{50} (72 h): > 100 mg/L nominal, based on: yield and growth rate NOE_rC: ≥ 100 mg/L (No statistically significant effect on growth rate or yield was observed after 72 hours of exposure to 100% of the water soluble fraction)	Not reliable because of a concentration loss below the LOD already after 24h; experimental result Test material: TFEE-5	Registration Dossier (Test laboratory, 2010b)

The registrant provided a GLP compliant test with *Pseudokirchneriella Subcapitata* according to OECD 201 with 72 hours of exposure. The highest test concentration had a loading rate of 100 mg/L and was regarded as containing 100% of the water soluble fraction (WSF) of TFEE-5 after 25 hours of magnetic stirring. This test concentration was than further diluted to obtain additionally 0.1, 1 and 10% of the WSF as test concentrations. Within the test, analytical monitoring was just conducted in the 100% WSF treatment at the start, after 24 hours and at the end of the test. After 24 hours the measured concentrations already dropped from 0.396 mg/L at the start of exposure to

below the limit of detection (0.14 mg/L). No significant effects on yield or growth was observed in any of the test concentrations. The registrant takes an EC_{50} for growth rate and yield of > 100 mg/L and a NOEC of >= 100 mg/L into account and concludes that TFEE-5 is not toxic to *P. subcapitata*. The validity criteria are fulfilled according to the registrant.

The eMSCA considers the provided test not reliable: According to the OECD Guidance Document No. 23, (OECD 23, 2019), WAFs are prepared individually and not by serial dilution of a single stock WAF. Following cessation of mixing and a period of settling (to allow phase separation) the aqueous phase, i.e. the WAF, is drawn off for testing. For the provided test, this was only the case for the highest test concentration and the test can be regarded as a limit test.

The eMSCA notes further that an exposure over 72 hours was not demonstrated: The test concentrations decreased below the limit of detection already after 24 hours.

Sediment organisms

No information available.

Other aquatic organisms

No information available.

7.8.2. Terrestrial compartment

No data regarding the terrestrial compartment is available in the literature or provided by the registrant.

7.8.3. Microbiological activity in sewage treatment systems

No data regarding microbial activity in sewage treatment systems is available in the literature or provided by the registrant.

7.8.4. PNEC derivation and other hazard conclusions

Due to the low aggregated tonnage, no PNECs are derived by the registrant. Since the studies provided are considered as unreliable, no PNECs are derived by the MSCA. However, the substance could be toxic to aquatic species.

7.8.5. Conclusions for classification and labelling

Based on the available data, no classification for the aquatic environment is necessary.

7.9. Human Health hazard assessment

Not evaluated.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and vPvB assessment

Persistence

The substance is not readily biodegradable (3% in 28 days). Based on BIOWIN predictions TFEE-5 is expected to be (very) persistent. TFEE-5 belongs to the group of perfluoropolyethers. These substances show nearly no potential for degradation, as described by Wang et al. (2015). The authors concluded that under environmentally relevant conditions perfluoroether chains are similarly resistant to abiotic (photolysis, reactions with OH radicals, and hydrolysis) and biotic degradation as the perfluoroalkyl chains.

The stability of organic fluorine compounds has been described in detail by Siegemund et al. (Siegemund et al., 2000): "When all valences of a carbon chain are satisfied by fluorine, the zig-zag-shaped carbon skeleton is twisted out of its plane in the form of a helix. This situation allows the electronegative fluorine substituents to envelope the carbon skeleton completely and shield it from chemical attack. Several other properties of the carbon-fluorine bond contribute to the fact that highly fluorinated alkanes are one of the most stable organic compounds. These include polarisability and high bond energies, which increase with increasing substitution by fluorine. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds. Properties that are exploited commercially include high thermal and chemical stability".

Therefore, the eMSCA concludes that TFEE-5 fulfils the P and the vP criteria.

Bioaccumulation

The log Kow of TFEE-5 given by the registrant is below 4.5 and therefore, TFEE-5 does not meet the screening criterion for B/vB. However this K_{ow} is contradictory to the EFSA opinion which reports a value of log K_{ow} = 9.4. This value is in the same range as a calculated K_{ow} based on COSMOtherm which has been conducted by the eMSCA. In an acute oral toxicokinetic screening study with rats TFEE-5 was not taken up from the digestive tract after a single dosage. The administered dose of TFEE-5 was recovered completely in the feces. This may be seen as an indicator for a low uptake. However an actual half-life as an indicator for bioaccumulation is not given by the registrant for this study. Therefore, the bioaccumulation concern is not regarded as clarified.

Toxicity

According to the registrant, TFEE-5 does not fulfil the criteria for toxicity of REACH Annex XIII. However, the short-term toxicity study on aquatic invertebrates is not acceptable according to the eMSCA. Furthermore, no long-term aquatic toxicity study on Daphnia is available. Based on REACH regulation Annex VII section 9.1.2 column 2, this study should be considered if a substance is poorly water-soluble. Based on opinion of the eMSCA, TFEE-5 and/or its impurities may be toxic to aquatic organisms.

Overall conclusion

Whether the PBT/vPvB criteria of REACH Annex XIII are fulfilled or not fulfilled cannot be concluded.

A broad restriction of PFAS (including TFEE-5) will be the most appropriate risk management measure to minimize concentrations of these persistent substances in the environment.

7.12. Exposure assessment

7.12.1. Human health

Not evaluated.

7.12.2. Environment

Assessment of exposure was conducted based on information provided by the registrant during a meeting between the experts from the eMSCA and the registrant. Since most of the available information are confidential, a detailed exposure assessment is presented in the confidential annex of this report. In addition, an assessment of the use of TFEE-5 in food contact materials is available which was performed by the EFSA Panel on Food contact Materials, Enzymes, Flavourings and Processing aids (CEF) (EFSA 2012).

TFEE-5 is used as a processing aid for fluoropolymer manufacture. Actions by the registrants such as as improved containment and increased use efficiency are considered by the eMSCA as important risk management measures to ensure a low risk of environmental exposure at the industrial site.

The substance consists of five C_3F_6O monomer units (TFEE-5). It could contain impurities up to 10%. According to the EFSA assessment, the measured residual content in final polymers, expressed as the sum of TFEE-5 and TFEE-6, 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. The total amount of polymers produced with the aid of TFEE-5 is unknown. Through the use of articles with such polymers, a wide dispersive release to the environment cannot be excluded. It is still unknown whether TFEE-5 and its constituents are evaporated to air or degraded during the heat processing of the polymers. According to the information provided by the registrant, the losses of TFEE-5 from the final, sintered polymers is low.

The EFSA assessment of the use of TFEE-5 in food contact materials concludes that 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 (EFSA, 2012). Consequently, a low exposure of humans to TFEE-5 via food should be considered. EFSA concluded that there is no concern for the consumers if TFEE-5 is only used as a polymer production aid, when processed at high temperatures.

7.12.3. Combined exposure assessment

Not evaluated.

7.13. Risk characterisation

Environment – aquatic environment

Only acute toxicity studies on aquatic invertebrates and algae are provided. No PNECs are derived by the registrant. Since the studies provided are considered as unreliable, no PNECs are derived by the eMSCA. However, the substance could be toxic to aquatic species.

7.14. References

ECHA (2017): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment. Version 3.0.

ECHA (2019): Member State Committee support document for identification of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) as substances of very high concern. https://echa.europa.eu/documents/10162/53fa6a5b-e95f-3128-ea9d-fa27f43b18bc

European Food Safety Authority (EFSA) (2012): 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 Journal 10 (12), 9 pp.

OECD (2019): Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. Series on Testing and Assessment No. 23 (Second Edition).

Siegemund G., Schwertfeger W., Feiring A., Smart B., Behr F., Vogel H., and McKusick B. (2000): Fluorine Compounds, Organic. In: Ullmann's Encyclopedia of Industrial Chemistry. Wiley-VCH Verlag GmbH & Co. KGaA. ISBN: 9783527306732. DOI: 10.1002/14356007.a11_349

Wang Z., Cousins I.T., Scheringer M., and Hungerbuehler K. (2015): Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: status quo, ongoing challenges and possible solutions. Environment international 75, 172-179

Young C.J., Hurley M.D., Wallington T.J., and Mabury S.A. (2006): Atmospheric lifetime and global warming potential of a perfluoropolyether. Environmental science & technology 40 (7), 2242-2246

7.15. Abbreviations

BCF	Bioconcentration factor
CSR	Chemical Safety Report
EC50	Half maximal effective concentration
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
eMSCA	evaluating Member state competent authority
LC50	Half maximal lethal concentration
NOEC	No observed effect concentration
PBT	Persistent, bioaccumulative, toxic
PFAA	Perfluoroalkyl acids
PFAS	Per- and polyfluoroalkyl substances
PFCA	Perfluoroalkyl carboxylic acid/ perflouroalkyl carboxylates
PFPE	Perfluoropolyethers
PFSA	Perfluoroalkyl sulfonic acid/ perfluoroalkyl sulfonates
PFOA	Perfluorooctanoic acid
SVHC	Substance of very high concern
vPvB	very persistent, very bioaccumulative