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

2-[methyl[(nonafluorobutyl) sulphonyl]amino] ethyl acrylate

EC No 266-733-5

CAS No 67584-55-8

Evaluating Member State(s): Germany

Dated: 30 September 2019

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
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D-44149 Dortmund, Germany

Year of evaluation in CoRAP: 2018

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

2-[methyl[(nonafluorobutyl) sulphonyl]amino] ethyl acrylate (N-MeFBSEA) was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/ vPvB properties
- Other hazard based concern: Degradation product(s) with probably equivalent level of concern to PBT/vPvB substances, having probable serious effects to the environment.
- Exposure of environment
- Wide dispersive use

No additional concerns were identified during the evaluation.

The assessment under substance evaluation was targeted on the environmental and ecotoxicological properties of the substance.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

N-MeFBSEA degrades to short-chain perfluoroalkyl carboxylic acids (e.g. perfluorobutanoic acid (PFBA)) and perfluorobutane sulfonic acid (PFBS) which have been subjected to regulatory focus: PFBS was recently assessed by the Norwegian Competent Authority (NO CA).

According to the published RMOA conclusion document of the NO CA for PFBS[2], identification of PFBS as a Substance of Very High Concern according to Article 57 f) and consecutive restriction for PFBS, its salts and related substances are suggested to be the most appropriate risk management options. Following the conclusion of the RMOA, the NO CA has prepared an Annex XV dossier for identification of PFBS and its salts as substances of very high concern (SVHC) according to Article 57 f) (Equivalent level of concern having probable serious effects on human health and the environment).[3]

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	X
Harmonised Classification and Labelling	X
Identification as SVHC (authorisation)	

[2] https://echa.europa.eu/documents/10162/1cb252bc-3952-3d5e-48b3-e78d5f5f0255

[3] https://echa.europa.eu/documents/10162/65f15ecf-b047-b2e1-351a-b79bbbb32082

Restrictions	X (within the scope of restriction of PFBS)
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

Based on the currently available ecotoxicity information on the substance, N-MeFBSEA fulfils the criteria for classification as Aquatic Chronic 2 (H411).

No entry in CLP Annex VI exists. According to the C&L Inventory (accessed on 24.10.2018), 16 notifiers classified the substance as Aquatic Chronic 2 and 186 notifiers did not classify the substance for environmental hazards.

4.1.2. Restriction

Degradation of N-MeFBSEA to short-chain perfluoroalkyl carboxylic acids (e.g. perfluorobutanoic acid (PFBA)) and perfluorobutane sulfonic acid (PFBS) can be demonstrated based on existing data.

PFBS was recently assessed by the NO CA. According to this assessment, the substance exhibits properties that give rise to an equivalent level of concern to PBT/vPvB substances, having probable serious effects to the environment. An Annex XV dossier has been prepared and submitted to ECHA to identify PFBS and its salts as SVHC. The public consultation on the dossier started in September 2019.[4]

Based on the "arrow head substance approach" as applied in the Annex XV Restriction Report of 11 April 2019 proposing a restriction for Perfluorohexane sulfonic acid (PFHxS) including its salts and precursors[5], precursors and their final degradation product (the "arrow head" substance into which a group of substances breaks down) should be addressed together by risk management measures. For PFBS (including its salts and precursors), restriction is suggested as one of the most appropriate risk management options. N-MeFBSEA is a precursor of this substance and thus will be within the scope of the planned restriction.

If necessary, the need for risk management measures tailored to N-MeFBSEA specifically will be assessed separately by the eMSCA based on the outcome of the PFBS restriction process.

[4] https://echa.europa.eu/de/substances-of-very-high-concern-identification/-/substance-rev/23901/term

[5] https://echa.europa.eu/documents/10162/a22da803-0749-81d8-bc6d-ef551fc24e19

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, see section 4.

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 a restriction on PFBS. N-MeFBSEA is, as a precursor, within the scope of this planned restriction proposal.	Unknown	NO CA
Annex VI dossier for harmonised classification and labelling on N-MeFBSEA	To be decided	DE CA

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

2-[methyl[(nonafluorobutyl) sulphonyl]amino] ethyl acrylate (N-MeFBSEA) was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/ vPvB properties
- Other hazard based concern: degradation product(s) with probably equivalent level of concern to PBT/vPvB substances, having probable serious effects to the environment
- Exposure of environment
- Wide dispersive use

No additional concerns were identified during the evaluation. The assessment under substance evaluation was targeted on the environmental and ecotoxicological properties of the substance.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Suspected PBT/vPvB properties	Based on currently available information the T criterion is not fulfilled. The substance is (very) persistent. Bioaccumulation potential (especially for air-breathing organisms) cannot be excluded.
Other hazard based concern – degradation products with probably equivalent level of concern to PBT/vPvB substances, having probable serious effects on the environment	Even if the substance is (very) persistent, degradation to short-chain perfluoroalkyl carboxylic acids (e.g. perfluorobutanoic acid (PFBA)) and perfluorobutane sulfonic acid (PFBS) has been proven. PFBS was recently assessed by the NO CA. PFBS exhibits properties that give rise to an equivalent level of concern having probable serious effects to the environment (Article 57 f). Based on the "arrow head substance approach", precursors and final degradation products should be addressed together by risk management measures. For PFBS (including its salts and precursors), restriction is suggested as one of the most appropriate risk management options.
Exposure of environment and wide dispersive use	Based on current knowledge, there is wide dispersive use of articles containing polymers based on N-MeFBSEA. Even with low residual concentrations of the substance itself in these polymers and articles, their degradation may eventually lead to the formation and environmental release of the extremely persistent "arrow head" substance PFBS.

7.2. Procedure

The substance evaluation of N-MeFBSEA started in March 2018.

The substance was originally selected for substance evaluation in order to clarify concerns about its suspected PBT/vPvB properties, the probable formation of degradation products(s) with a probable equivalent level of concern to PBT/vPvB substances and the potential exposure of the environment and wide dispersive use.

The evaluation was conducted by assessing the Chemical Safety Reports (CSRs) of N-MeFBSEA and the degradation product N-MeFBSE and the eMSCA's own literature search.

In June 2018, the eMSCA invited the registrant to clarify some questions and uncertainties in writing. The information provided by the registrant was assessed and taken into account while evaluating the substance.

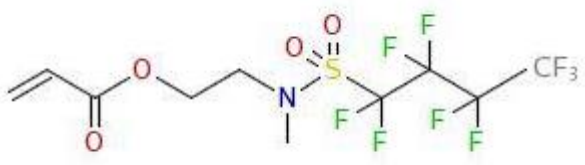
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	2-[methyl[(nonafluorobutyl)sulphonyl]amino]ethyl acrylate
EC number:	266-733-5
CAS number:	67584-55-8
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_{10}H_{10}F_9NO_4S$
Molecular weight range:	411.24 g/mol
Synonyms:	2-Propenoic acid, 2- methyl (nonafluorobutyl)sulfonyl amino ethyl ester 2-(N-Methylperfluorobutanesulfonamido)ethyl acrylate 2-(N-Methylperfluorobutylsulfonamido)ethyl acrylate N-MeFBSEA

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20 °C and 101.3 kPa	White waxy solid; Visual interpretation
Vapour pressure	0.25 Pa at 25 °C, dynamic method
Water solubility	2.02 mg/L at 22 °C
Partition coefficient n-octanol/water (Log Kow)	4.19 at 22 °C, EPA OPPTS 830.7550 (Partition Coefficient, n-octanol/H_2O, Shake Flask Method)
Granulometry	Not applicable
Stability in organic solvents and identity of relevant degradation products	Not applicable
Dissociation constant	Not applicable No ionizable groups

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

N-MeFBSEA is manufactured and is further used as a monomer in polymerization processes. Additional information is provided in a confidential annex.

Table 7

USES	
	Use(s)
Uses as intermediate	Yes
Formulation	No
Uses at industrial sites	Yes
Uses by professional workers	No
Consumer Uses	No

Article service life	No

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

No entry in Annex VI of CLP Regulation exists.

7.6.2. Self-classification

• In the registration:

- Skin Sens. 1B (H317)

- Aquatic Chronic 2 (H411)

• The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:

- Skin Sens. 1 (H317)

7.7. Environmental fate properties

7.7.1. Degradation

7.7.1.1. Abiotic degradation

Table 8

SUMMARY OF STUDIES ON ABIOTIC DEGRADATION		
Method	**Results**	**References/ remarks**
EPA OPPTS 835.2110 (Hydrolysis as a Function of pH)	Preliminary test (50 °C), duration: 5 days pH 7: half-life (50 °C) = 22.078 days half-life (25 °C) = 220.78 days (extrapolation from half-life at 50 °C) transformation products: at pH 4,7, and 9: 2-(N-methylperfluorobutanesulfonamido) ethanol (N-MeFBSE, CAS No 34454-97-2) at pH 9: 2-N-methylperfluorobutanesulfonamide (N-MeFBSA) and perfluorobutanesulfonamide (FBSA) **No PFBS detected in all buffers**	Registration dossier Reliability 1 (key study)
AOPWIN (v1.92)	Half-life = 16.7 hours (24-hour day) Half-life = 5.6 hours (12-hour day) Degradation rate constant:	Registration dossier Reliability2 (key study)

	0.000001986 cm^3 $molecule^{-1}$ d^{-1} for reaction with OH radicals	

N-MeFBSEA has a hydrolytic half-life of 220.78 days at 25 °C. The half-life was determined from the appearance of the degradation product. Four targeted hydrolysis compounds were analyzed by HPLC/MS. Only N-MeFBSE was found as hydrolysis product at pH 7, and was used to calculate the hydrolysis half-life. The half-life was longer under acidic (586.92 days) and basic conditions (15.14 years).

Nielsen investigated theoretical abiotic degradation pathways of potential PFBS precursors (Nielsen, 2017). The study includes PFBS-related sulfonamides like MeFBSEA. No experimental information concerning solubility or hydrolytic lifetimes was found in the open literature. The author assumes that PFBS-related sulfonamides will undergo slow hydrolysis resulting in release of PFBS.

Assessment of abiotic degradation of hydrolysis transformation products:

Table 9

SUMMARY OF STUDIES ON ABIOTIC DEGRADATION OF HYDROLYSIS TRANSFORMATION PRODUCTS			
Transformation product	**Method**	**Results**	**References /remarks**
N-MeFBSE, CAS No 34454-97-2	OECD 111 (Hydrolysis as a Function of pH)	Preliminary test (50 °C), duration: 5 days pH 4, 7, 9: half-life (25 °C) ≥ 609.8 days (estimation method: statistical evaluation of standard deviation to determine the reliability of rate constants determined over all pH levels) half-life (25 °C) ≥ 824 days (estimation method: using N-MeFBSE initial concentration and the LOQ of PFBS) transformation products: potential hydrolysis products were all below LOQ: N-MeFBSA (< 10 µg/L) FBSA (< 9.997 µg/L) **PFBS (< 25 µg/L)** **PFBA (< 24.75 µg/L)**	Registration dossier for N-MeFBSE Reliability 2
2-N-methylperfluorobutane-sulfonamide (N-MeFBSA) $C_4F_9SO_2NH\mathbf{CH_3}$	Atmospheric photo-oxidation	Atmospheric lifetime: 20-50 days stable products, e.g.: **PFBA: 0.33%** **PFPrA: 0.11%** **TFA: 0.09%**	(Martin et al., 2006) Tested with N-ethyl perfluoro-butansulfonamide (N-EtFBSA) $C_4F_9SO_2NH\mathbf{CH_2CH_3}$ Reliability 2

N-MeFBSE, CAS No 34454-97-2	Atmospheric photo-oxidation	Atmospheric lifetime: 2 days stable products, e.g.: **PFCAs: 10%** **PFBS: 1%**	(D'eon et al., 2006) Reliability 2

Martin et al. studied atmospheric photo-oxidation of N-ethyl perfluorobutansulfonamide (N-EtFBSA, $C_4F_9S(O)_2NHCH_2CH_3$) initiated by OH radicals and atomic Cl (smog chamber experiment) (Martin et al., 2006). The atmospheric lifetime of N-EtFBSA in the gas-phase (reaction with OH radicals) is estimated to be 20-50 days. The authors observed that atomic Cl are 23 times more reactive towards N-EtFBSA than OH radicals. Therefore, atomic Cl was used in place of OH radicals for product formation experiments. Product formation experiments with OH radicals would proceed too slowly to produce secondary products in the experimental system. Nevertheless, Cl atoms and OH radicals are expected to react with N-EtFBSA via hydrogen abstraction to give the same products (although not necessarily in the same yield). Based on chlorine atom initiated oxidation, $C_4F_9S(O)_2NHC(O)CH_3$, $C_4F_9S(O)_2NHCH_2CHO$ and $C_4F_9S(O)_2NHCHO$ were identified by Fourier transfer infrared spectroscopy (FTIR) as intermediates, and sulfur dioxide (SO_2), carbonyl fluoride (COF_2) and perfluoroalkyl carboxylic acids (PFCAs) as stable products. Three PFCAs were detected above the limit of the blank: 0.33% perfluorobutanoic acid (PFBA), 0.11% perfluoropropanoic acid (PFPrA), and 0.09% trifluoroacetic acid (TFA) of the molar balance, respectively. At the same time, only 0.65% of the starting material had been transformed to COF_2. Extrapolation of these results suggests that 45% of the carbon in the perfluoroalkane chain will ultimately be incorporated into PFCAs upon complete oxidation, while the remaining fraction is expected to form COF_2 (timeframe not given). PFBS was not detected in any sample. D'eon et al. suggested that the atmospheric lifetime of N-MeFBSA is likely to be similar to that of N-EtFBSA (D'eon et al., 2006). The atmospheric lifetime of N-EtFBSA underestimates that of N-MeFBSA due to the fewer abstractable hydrogens and so fewer reactive sites. The authors concluded that the atmospheric lifetime of N-MeFBSA is >20 days.

D'eon et al. measured the gas-phase reaction of N-MeFBSE with OH radicals (D'eon et al., 2006). An atmospheric lifetime of approximately two days were determined. The following products were identified by in situ FTIR spectroscopy and offline GC-MS and LC –MS/MS analysis: N-MeFBSA (N-dealkylation product), COF_2, PFBA, PFPrA, TFA and PFBS. The concentration of PFBA and PFPrA increased during the course of the reaction. For quantification of PFCAs and PFBS a mass balance was carried out. After 50% consumption of N-MeFBSE, the cumulative concentration of PFCAs and PFBS accounted for approximately 10 and 1%, respectively. In addition, the authors performed Cl-atom initiated oxidation. The products of this oxidation were similar to those observed in the OH-radical initiated oxidation experiments. PFCAs and PFBS were detected with similar concentration profiles.

Nielsen investigated theoretical abiotic degradation pathways of potential PFBS precursors (Nielsen, 2017). The study includes commercially available PFBS sulfonamides like the hydrolysis transformation products of N-MeFBSEA: N-MeFBSE, N-MeFBSA and FBSA. No experimental information concerning solubility or hydrolytic lifetimes was found in the open literature. The author assumes that PFBS-sulfonamides will undergo slow hydrolysis resulting in release of PFBS. Based on Martin et al. 2006 and D'eon et al. 2006, Nielsen concluded that PFBS sulfonamides undergo photo-oxidation, which will result in the release of PFCAs.

7.7.1.2. Biodegradation

Biodegradation of N-MeFBSEA was tested in one screening test according to OECD Guideline 301 B. From the results it follows that the substance is not readily biodegradable. No simulation test is available in the registration dossier.

Table 10

SUMMARY OF SCREENING TESTS		
Method	**Results**	**References/ remarks**
OECD Guideline 301 B (Ready Biodegradability: CO_2 Evolution Test) non-adapted	% degradation of test substance: 0-3 after 28 days (CO_2 evolution) Toxicity control: > 25% biodegradation in 14 days Reference substance: > 60% degradation by day 14	Registration dossier Reliability 1 (key study)

Assessment of biotic degradation of hydrolysis transformation products:

Table 11

SUMMARY OF STUDIES ON BIODEGRADATION OF HYDROLYSIS TRANSFORMATION PRODUCTS			
Transformation product	**Method**	**Results**	**References/ remarks**
N-MeFBSE, CAS No 34454-97-2	OECD 301B (Ready Biodegradability: CO_2 Evolution Test) non-adapted	% degradation of test substance: 0-2 after 28 days (CO_2 evolution) Toxicity control: > 25% biodegradation in 14 days Reference substance: > 60% degradation by day 14	Registration dossier for N-MeFBSE Reliability 1 (key study)
N-MeFBSE, CAS No 34454-97-2	EPA OPPTS 835.3200 (Zahn-Wellens / EMPA Test) non-adapted	% primary degradation of test substance: 37-49% (test mat. analysis) after 7 days 96-97% (test mat. analysis) after 28 days Abiotic control: 4% degradation after 28 days Reference substance: > 70% degradation by day 14 Transformation products after 28 days: N-MeFBSE-Acid: 97.4% N-MeFBSAmide: 1.2% FBSA: 0.49% **PFBS: 0.18%** **PFBA: 0.17%**	Registration dossier for N-MeFBSE Reliability 2 (supporting study)

For the hydrolysis transformation product of N-MeFBSEA, the alcohol N-MeFBSE, two biodegradation studies are available. The substance is not readily biodegradable as only 0-2% CO_2 evolution was observed after 28 days. Based on inherent biodegradation test according to Zahn Wellens/EMPA Test the substance is inherently (primarily) biodegradable, not fulfilling specific criteria. The main transformation product was N-MeFBSE-acid at 97.4%. PFBS and PFBA were observed at 0.18% and 0.17%, respectively.

7.7.1.3. Summary and discussion on degradation

The registered substance hydrolyses slowly with a half-life of 221 days at 25 °C. The following degradation products were observed: N-MeFBSE, N-MeFBSA and FBSA.

An atmospheric half-life of 5.6 hours was determined by AOPWIN.

N-MeFBSEA is not readily biodegradable (0-3% after 28 days). No simulation tests are available. Based on the available information, N-MeFBSEA is expected to be (very) persistent.

Nevertheless, eventual degradation to short-chain perfluoroalkyl substances has been proven. The hydrolysis products N-MeFBSE and N-MeFBSA will be further degraded via abiotic degradation and biodegradation to PFBS and short-chain PFCAs like PFBA, PFPrA and TFA. Figure 1 illustrates the results of Tables 9-11.

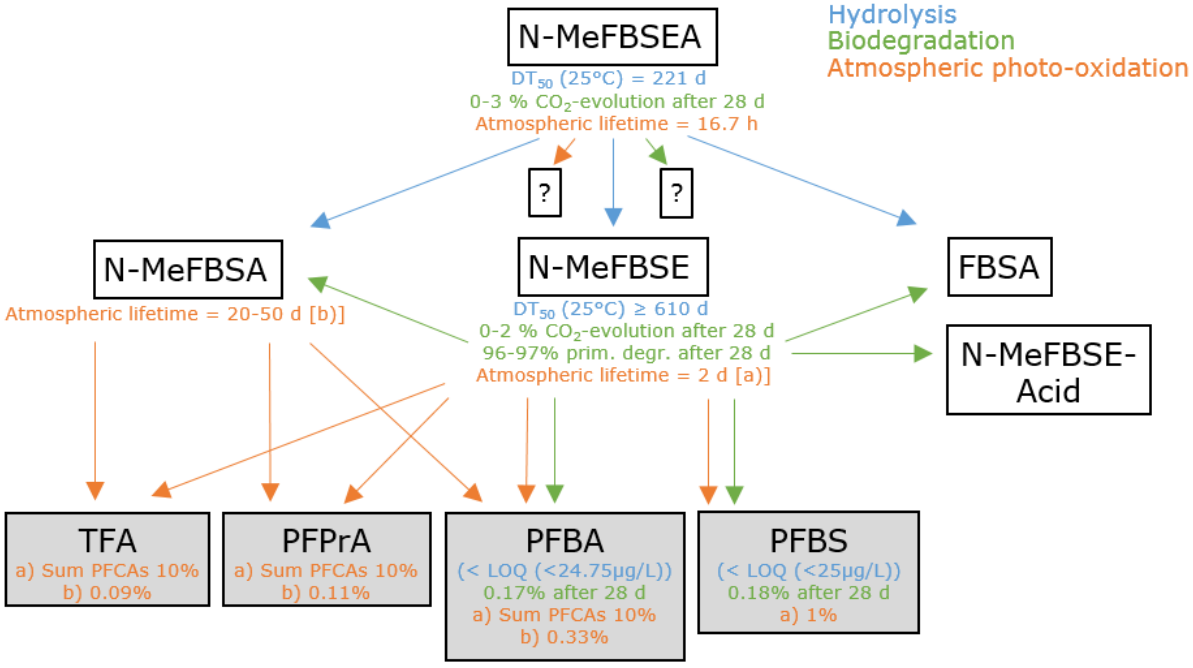


Figure 1: Potential degradation pathways (blue arrows: hydrolysis products; green arrows: biodegradation products; orange arrows: products of atmospheric degradation; a) atmospheric lifetime and products of atmospheric degradation for N-MeFBSA; b) atmospheric lifetime and products of atmospheric degradation for N-MeFBSE) [References: Registration dossiers for N-MeFBSEA, N-MeFBSE, Martin et al., 2006, D'eon et al., 2006]

The formation of PFBS during biodegradation of N-MeFBSEA was also predicted by QSARs (CATALOGIC v.5.11.13, EAWAG-BBD Pathway Prediction System). However, these prediction models should be used carefully for per- and polyfluoroalkyl substances. The Pathway Prediction System of EAWAG should not be used for highly fluorinated compounds (those that have more fluorine atoms than non-fluorine atoms bonded to carbon) because the rules used by the system do not accurately predict the unique

characteristics for these substances. CATALOGIC automatically checks the applicability domain of substances. The structure of N-MeFBSEA was out of the structural domain as 28% were unknown fragments.

Potential precursor substances of PFBA and PFBS were screened using QSAR Toolbox v4.1. For N-MeFBSEA, PFBS was found as a transformation product by microbial transformation.

7.7.2. Environmental distribution

Adsorption

The adsorption of N-MeFBSEA was determined according to the OECD 121 test guideline using the HPLC method (registration dossier). 15 peaks were present in the chromatogram. The major peak contributes to 65% of the total peak area. The log K_{OC} for this component was estimated to be 4.03 at 35 °C. Six further peaks were present at >1% of the total peak area. Log K_{OC} values for these components range from <1.26 to 4.23.

Furthermore, the registrant calculated K_{OC} values using KOCWIN v2.00. Based on MCI (Molecular Connectivity Index) method, log K_{OW} method and log K_{OW} method from European Chemicals Bureau, log K_{OC} values in the range of 3.25 to 3.49 were determined.

Based on the determined and estimated log K_{OC} values, it is likely that N-MeFBSEA will adsorb strongly to organic matter in sediment, soil and sewage sludge.

Volatilization

Based on Henry's Law constant of 49.6 Pa m³/mol (25 °C) N-MeFBSEA would volatilize from water.

7.7.3. Bioaccumulation

An experimental log K_{OW} of 4.19 (according OECD 107) and a calculated BCF of 291.5 L/kg (EpiSuite 4.11; Arnot-Gobas-Model) indicate that N-MeFBSEA is not bioaccumulative according to the screening criteria for PBT assessment outlined in ECHA Guidance R.11 (European Chemicals Agency, 2017). The calculated log K_{OA} of 7.3 (EpiSuite 4.11; Arnot-Gobas-Model) in combination with the log K_{OW} indicate a potential for terrestrial bioaccumulation (ECHA Guidance R.11 (European Chemicals Agency, 2017)). However, this substance group is not in the domain of EpiSuite 4.11. Therefore the calculated values are considered as not sufficiently reliable.

The elimination half-life of parent and any potentially fluorinated metabolites from both rat serum and liver was determined by measurement of total fluorine and is approximately 21 hours after administration of a single oral gavage dose (study performed in 2002 and reported in the registration dossier).

7.8. Environmental hazard assessment

The following chapter contains ecotoxicological information on the evaluated substance (N-MeFBSEA). The results of the available studies give no indication that, on a screening level, the T criterion might be fulfilled based on ecotoxicological data. However, it should be noted that the registration dossier which is the basis for this conclusion contains inconsistencies regarding the solubility of the substance. The water solubility differs between various test media prepared for ecotoxicity testing by a factor of > 3, although the preparation procedure was the same. This is a crucial point regarding the read-across from acute to chronic effects and therefore is important for the assessment of the T criterion.

The effect concentration EC_{50} resulting from the test on aquatic invertebrates with daphnia is used for assessing the screening criterion for T. Based on this invertebrate test, it can be assumed that higher concentrations of the test substance in the test medium can be achieved within the fish and algae study than measured in the respective tests given in the registration dossier. Therefore, it cannot be ruled out that fish and algae could show a more sensitive response to the test substance and an accordingly lower effect concentration than invertebrates.

7.8.1. Aquatic compartment (including sediment)

7.8.1.1. Fish

Table 12

SUMMARY OF EFFECTS ON FISH			
Substance	**Method/Organism**	**Results**	**Reference**
N-MeFBSEA	OECD Guideline 203 (Fish, Acute Toxicity Test) Limit test Semi-static *Danio rerio*	LC_{50} (96 h): > 0.32 mg/L (meas. (arithmetic mean)) based on: mortality	Registration dossier

No long-term toxicity test on fish is available.

7.8.1.2. Aquatic invertebrates

Table 13

SUMMARY OF EFFECTS ON AQUATIC INVERTEBRATES			
Substance	**Method/Organism**	**Results**	**Reference**
N-MeFBSEA	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) Static *Daphnia magna*	EC_{50} (48 h): 1.2 mg/L (meas. (Geom. Mean)) (based on: immobilisation)	Registration dossier

No long-term toxicity test on aquatic invertebrates is available.

7.8.1.3. Algae and aquatic plants

Table 14

SUMMARY OF EFFECTS ON ALGAE			
Substance	**Method/Organism**	**Results**	**Reference**
N-MeFBSEA	OECD Guideline 201 (Alga, Growth Inhibition Test) Static	EC_{50} (72 h): > 0.34 mg/L (meas. TWA) (based on: growth rate)	Registration dossier

	Pseudokirchnerella subcapitata (algae)		

7.8.1.4. Sediment organisms

No relevant information is available.

7.8.1.5. Other aquatic organisms

No relevant information is available.

7.8.2. Terrestrial compartment

Not relevant within the scope of the PBT/vPvB assessment.

7.8.3. Microbiological activity in sewage treatment systems

Table 15

SUMMARY OF EFFECTS ON MICROORGANISMS			
Substance	**Method/Organism**	**Results**	**Reference**
N-MeFBSEA Sludge from municipal sewage treatment plant	OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test) Limit test Static	NOEC (3 h): 1000 mg/L (nominal) (based on: respiration rate)	Registration dossier

7.8.4. Conclusions for classification and labelling

For N-MeFBSEA the environmental classification as Aquatic Chronic 2 as stated by the registrant is supported by the eMSCA.

7.9. Human Health hazard assessment

Not evaluated.

7.10. Assessment of endocrine disrupting (ED) properties

7.10.1. Endocrine disruption – Environment

No data on endocrine disrupting properties are available for N-MeFBSEA. However, the degradation products of N-MeFBSEA might possess endocrine disrupting properties. Several studies indicate effects on the hypothalamus-pituitary-thyroid axis by PFBS (cf. Annex XV dossier on PFBS and its salts[6]; (Vongphachan et al., 2011)) and PFBA (Naile et al., 2012).

[6] https://echa.europa.eu/documents/10162/65f15ecf-b047-b2e1-351a-b79bbbb32082

7.10.2. Endocrine disruption - Human health

Not evaluated.

7.10.3. Conclusion on endocrine disrupting properties

No data on endocrine disrupting properties for the environment are available for N-MeFBSEA and no data on endocrine disrupting properties regarding human health was evaluated. Therefore, at present it cannot be concluded whether N-MeFBSEA is an endocrine disrupting substance, though degradation products of N-MeFBSEA might possess endocrine disrupting properties.

7.11. PBT and VPVB assessment

Persistence

N-MeFBSEA hydrolyses slowly with a half-life of 221 days at 25 °C. The substance is not readily biodegradable. No simulation tests are available. Based on the available information N-MeFBSEA is expected to be (very) persistent.

Nevertheless, the potential for degradation to short-chain perfluoroalkyl carboxylic acids (e.g. PFBA) and PFBS has been proven.

Bioaccumulation

Based on the log K_{OW} N-MeFBSEA is not considered to be bioaccumulative for aquatic organisms. In combination with the log K_{OA} a potential for bioaccumulation in terrestrial organisms may be indicated according to REACH Annex XIII screening criteria. However, low elimination half lives in rat indicate a low potential for terrestrial bioaccumulation.

Toxicity

No short-term effects were observed in fish and algae for N-MeFBSEA. Only for invertebrates short-term effects were observed. No long-term data for fish or aquatic invertebrates are available.

Based on the short-term toxicity data on aquatic organisms (lowest EC_{50} = 1.2 mg/L), N-MeFBSEA does not fulfil the screening T criterion of Annex XIII. As no data on long-term toxicity is available, the T criterion according to Annex XIII cannot be conclusively assessed at the moment.

Overall conclusion

The PBT criteria of REACH Annex XIII are not fulfilled. However, the substance is (very) persistent. The potential for bioaccumulation was only ruled out based on the log K_{OW} value, i.e. on a screening level. The potential for terrestrial bioaccumulation is indicated by high log K_{OA} but ruled out by low elimination half lives in rats.

Short-chain perfluoroalkyl carboxylic acids (e.g. PFBA) and PFBS have been proven as degradation products. PFBS, for example, exhibits properties that give rise to an equivalent level of concern to PBT/vPvB substances, having probable serious effects to the environment (Article 57 f).

7.12. Exposure assessment

The release of N-MeFBSEA into the environment may occur during manufacture of the substance and the subsequent polymerisation step. Due to a certain content of unbound N-MeFBSEA in the polymers, the substance may also be released into the environment during the service life of the products.

Synthesis and subsequent polymerisation of N-MeFBSEA take place under the same operating conditions. Losses during manufacturing and the polymer synthesis are below 0.1%. After the cleaning step the measured concentration of N-MeFBSEA in the waste water was below the LOD (< 0.04 mg/L). Waste air and waste water are cleaned with granulated activated carbon (GAC) filters. The GAC filters as well as solid wastes including sludge is incinerated. However, the retaining of possible degradations products, like PFBA, by the GAC filtration could be lower than for N-MeFBSEA. In conclusion, the emission of N-MeFBSEA into the environment at the manufacturing site may be below a certain level of concern.

The content of unbound N-MeFBSEA monomers in final products is below 0.1%. A leaching out from products and articles is expected to be very low. Judging from information available for other PFAS-containing polymers, the degradation pathways outlined above for formation of PFBS from monomeric N-MeFBSEA may also be relevant for the substance once it has polymerised. Therefore, release of PFBS from articles containing the substance during their service life cannot be excluded.

N-MeFBSEA was monitored in a screening programme conducted by Norway in 2016. In all investigated compartments (wastewater from waste water treatment plants influent, effluent and sludge as well as in surface water, sediment and biota in Oslofjord and Lake Mjøsa, samples from the indoor environment like house dust and indoor air) the concentration of N-MeFBSEA was below the limit of detection of 10-100 ng/g or ng/L (Schlabach et al., 2017).

7.13. Risk characterisation

At the moment there is no clear indication for a risk to the environment by the substance itself, considering the currently available hazard- and exposure data. However, degradation products of N-MeFBSEA (e.g. PFBS) may exhibit an equivalent level of concern to PBT/vPvB substances and cause probably serious effects to the environment, as pointed out by the Norwegian Competent Authority in the RMOA conclusion document for PFBS[7].

7.14. References

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[7] https://echa.europa.eu/documents/10162/1cb252bc-3952-3d5e-48b3-e78d5f5f0255

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7.15. Abbreviations

Abbreviations of the chemical names used in this document

FBSA	perfluorobutanesulfonamide CAS No 30334-69-1 $C_4F_9SO_2$-NH_2
N-EtFBSE	(N-ethylperfluorobutanesulfonamido)ethanol $C_4F_9SO_2N(C_2H_5)CH_2CH_2OH$
N-MeFBSA	N-methylperfluorobutanesulfonamide CAS No 68298-12-4 $C_4F_9SO_2$-$NHCH_3$
N-MeFBSEA	2-[methyl[(nonafluorobutyl)sulphonyl]amino]ethyl acrylate CAS No 67584-55-8 $C_4F_9SO_2$-$N(CH_3)CH_2CH_2OCOCHCH_2$ $C_{10}H_{10}F_9NO_4S$
N-MeFBSE	2-(N-methylperfluorobutanesulfonamido) ethanol 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methylbutane-1-sulphonamide (IUPAC-name) CAS No 34454-97-2 $C_4F_9SO_2$-$N(CH_3)CH_2CH_2OH$
N-MeFBSE-acid	N-methylperfluorobutanesulfonamido acetate
PFAS	Per- and polyfluoroalkyl substance
PFBA	Perfluorobutanoic acid CAS No 375-22-4 C_3F_7COOH
PFBS	Perfluorobutane sulfonic acid CAS No 375-73-5 $C_4F_9SO_3H$
PFCA	Perfluoroalkyl carboxylic acid
PFPrA	Perfluoropropanoic acid CAS No 422-64-0 C_2F_5COOH
TFA	Trifluoroacetic acid CAS No 76-05-1 CF_3COOH

Other Abbreviations

BCF	Bioconcentration factor
CLP	Classification, Labelling and Packaging
CoRAP	Community rolling action plan
CSR	Chemical safety report
EC_{50}	Half maximal effect concentration
eMSCA	Evaluating Member State Competent Authority
GAC	Granulated activated carbon
GC-MS	Gas chromatography mass spectrometry
HPLC/MS	High-pressure liquid chromatography / mass spectrometry
K_{OA}	n-octanol/air partition coefficient

K_{OC}	Organic carbon normalized adsorption coefficient
K_{OW}	n-octanol/water partition coefficient
LC-MS	Liquid chromatography / mass spectrometry
LOD	Limit of detection
LOQ	Limit of quantification
MS	Mass spectrometry
NOEC	No observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative and toxic
RMOA	Regulatory management option analysis
SVHC	Substance of very high concern
TWA	Time weighted average
vPvB	Very persistent, very bioaccumulative