Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Perfluamine
EC Number:	206-420-2
CAS Number:	338-83-0
Authority:	BE MSCA
Date:	22/03/2016

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

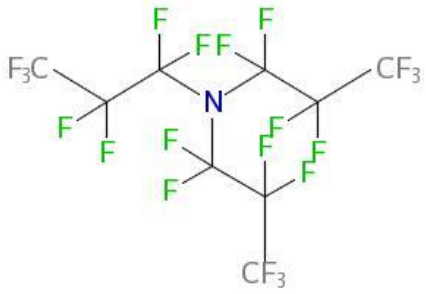
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	perfluamine
IUPAC name (public):	1,1,2,2,3,3,3-heptafluoro-N,N-bis(heptafluoro propyl)propan-1-amine
Index number in Annex VI of the CLP Regulation:	not listed
Molecular formula:	$C_9F_{21}N$
Molecular weight or molecular weight range:	521.07 g/mole
Synonyms:	

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

Structural formula:



Other relevant information about substance composition :

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1.2 Similar substances/grouping possibilities

In the registration dossier the substance is included in a category approach with other perfluorinated substances, such as :
Perfluorohexane, CAS# 1064697-81-9
Perfluoroheptane, CAS# 1064698-16-3
Perfluorotributylamine, CAS# 1064698-37-8
Perfluoro-N-methylmorpholine, CAS# 382-28-5
Perfluoro-N-C1,3-alkyl morpholine, CAS# 1093615-61-2
Perfluoro-C6,8-furans, pyrans and acyclic ethers , CAS# 1064698-52-7

Read across data is included in the dossier for several endpoints in relation to physico-chemical properties, ecotoxity en toxicity tests. The appropriateness of the read-across approach needs further analysis and seems to be not valid.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
sses unde r other EU legisl	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	

[1] Please specify the relevant entry.

	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

3.1.2 Self classification

- In the registration:

  None

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

  Acute Tox. 4 H302

  Acute Tox. 3 H311

Eye Irrit. 2, C≥10% H319

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently no proposal for harmonised classification.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

Dissemination website was consulted on 28 May 2015.

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

4.2 Overview of uses

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	Not mentioned in the registration dossier(s)
Formulation	PROC 5 - PROC 8b - PROC 9

[2] *Please provide here the date when the dissemination site was accessed.*

Uses at industrial sites	PROC 8a - PROC 8b - PROC 9 - PROC 1 - PROC 4 - PROC 15 - PROC 13
Uses by professional workers	PROC 1 - PROC 15 - PROC 8a - PROC 8b - PROC 9
Consumer Uses	Not mentioned in the registration dossier(s)
Article service life	Not mentioned in the registration dossier(s)

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☒ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)

Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☒ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[3] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

This substance belongs to the class of perfluorinated compounds and a few members of this class of substances are already identified as PBT or vPvB substances. As indicated in the argumentation documents supporting the identification as a PBT or vPvB-substance (cfr. annex XV documents for PFOA, PFNA, PFDA), these perfluorinated compounds show specific physico-chemical properties which distinguish them clearly from other non-(per/poly)fluorinated organic compounds. Certainly with regard to the bioaccumulative character of these compounds the usual assessment techniques are not reliable and cannot be used to come to definitive conclusions for this substance.

In the registration data, an evaluation of the potential PBT/vPvB character of this substance is presented and it is concluded by the Registrant(s) that this substance does not meet the PBT criteria. However, after evaluation of the argumentation presented by the Registrant(s), one has to conclude that several statements and arguments are not correctly substantiated and are at least premature. In general the data presented are not sufficient to take away the PBT/vPvB concern.

For many endpoints read-across data are presented while the validity of this approach is not established. Further, it should be noted that the correctness of the current assessment of the distribution of the substance in the environment is doubtful and cannot be accepted in the present form. Besides, at the moment the bioaccumulation profile of this substance is assessed based on fat solubility characteristics while it is generally accepted that per-and polyfluorinated compounds bioaccumulate by protein binding processes.

For the various endpoints the following observations can be made:

Persistence

There is no indication of biodegradation or abiotic degradation based on the available information In the absence of additional information, it is appropriate to consider this substance as very persistent. As a result substantial levels of the substance in a condensed state could arise in the environment over long periods of time.

Bioaccumulation

There are no bioaccumulation tests available on any species. It should be pointed out that perfluorinated compounds tend to bioaccumulate via protein binding processes and that these bioaccumulation processes cannot be modeled via log Kow-values. Certainly for air-breathing organisms bioaccumulation is a plausible process and should be explored.

Toxicity

For this substance only an acute daphnia magna test is available. In this test no effects were seen up to the water solubility. For terrestrial species no tests are available. Consequently, no definitive conclusion can be formulated regarding the ecotoxicological properties of this substance

Overall, for the moment no conclusion can be drawn in relation to the fate and the distribution of the substance in the environment. Further the bioaccumulation potential, mainly in air-breathing organisms, remains unclear. Both aspects should be further examined in order to come to a reliable conclusion on the PBT/vPvB properties of this substance.

5.4 Preliminary indication of information that may need to be requested t clarify the concern

☐ Information on toxicological properties	☒ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

Information that allows to assess in a reliable way the distribution of the substance between the various environmental compartments.
Information that allows to assess the bioaccumulation potential.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)

Depending on the outcome of the evaluation any of the above mentioned risk management measures could be initiated if warranted.

If concerns for PBT/vPvB properties are confirmed by additional testing, an identification as SVHC belongs to potential follow-up actions.