Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine
Chemical Group:	perfluorinated compound
EC Number:	473-390-7
CAS Number:	NA
Submitted by:	BE CA
Date:	17/03/2015

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

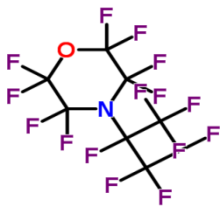
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	$C_7F_{15}NO$
Molecular weight or molecular weight range:	399.0 g/mol
Synonyms/Trade names:	FC-770

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

Structural formula:



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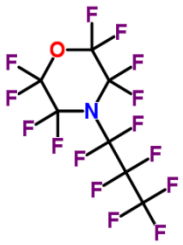

1.2 Similar substances/grouping possibilities

No info

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

NA for FC-770

Applicable for cell crude of FC-770: harmonised classification applicable based on the classification of HF (impurity):

Acute Tox 4 (oral); H302: Harmful if swallowed

Acute Tox 3 (dermal); H311: Toxic in contact with skin

Eye Irrit. 2; H319: Causes serious eye irritation

2.2 Self classification

- In the registration

NA

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

NA

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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

☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System
Manufacture of cell crude. Industrial use in closed systems Industrial use in closed batch processes Industrial spraying Industrial product transfer Industrial solvent use in closed systems Industrial use in open systems Professional use in closed systems Professional product transfer Professional use in closed batch processes Professional use in open systems			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Information on other completed/ongoing regulatory processes was not found.	

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[1]	
☐ 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)

The substance belongs to the class of perfluorinated compounds and several members of this group of substances are already identified as PBT or vPvB substances. As indicated in the argumentation documents supporting the identification as PBT or vPvB substances (annex XV), these perfluorinated compounds show specific intrinsic physico-chemical properties which distinguish them clearly from other non-perfluorinated organic compounds.

In the registration data, an evaluation of the potential PBT/vPvB character of the substance is presented and it is concluded by the registrant that the substance does not meet the PBT-criteria. However, after evaluation of the argumentation one has to conclude that some statements are premature and that the data presented are not sufficient to take away the PBT concern.

The substance shows substantial volatility and a very low water solubility, resulting in a high Henry's Law constant. This observation is used by the registrant to state that the substance will only partition to the air compartment and not to other environmental compartments after release. However, in absence of experimentally measured values for log K_{oc} and log K_{oa}, there remains a concern that the substance is distributed in a relevant amount to soil or sediment and so the environmental fate of the substance should be clarified by targeted specific testing. One should

[1] 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

take into account the fact that these compounds show an extremely persistent profile and therefore substantial levels in the soil and/or sediment compartments over long periods of time could prove to be a realistic scenario.

With regard to the bioaccumulation potential, it should be pointed out that perfluorinated compounds, in contrast to a great majority of organic compounds, tend to accumulate in species via protein binding processes. These accumulation processes cannot be modeled via log K_{ow} values and as no experimental bioaccumulation test is presented on any species, it is with the presently available information not possible to conclude on the bioaccumulation profile of the substance. In some cases a toxicokinetic study on mammals could be instructive with regard to bioaccumulation potential, but no toxicokinetic study is available for this substance.

Overall it is appropriate to conclude that the fate of the substance in relation to its distribution towards soil, sediment and mainly air breathing organisms is not sufficiently clear.

5.4 Preliminary indication of information that may need to be requested to 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 for air breathing species.

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.