

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate
Chemical Group:	
EC Number:	700-323-3
CAS Number:	908020-52-0
Submitted by:	Germany
Date:	17/03/2015

Note

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

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	Ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	
Molecular weight or molecular weight range:	
Synonyms/Trade names:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

1.2 Similar substances/grouping possibilities

None

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI of the CLP regulation.

2.2 Self classification

- In the registration:
Acute Tox. 4 (H302); Eye Damage 1 (H318); Repr. 2 (H361)
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Not included in the C&L inventory

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal for harmonised classification is publically available.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input checked="" type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Not available on ECHA dissemination site.			

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

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>The substance is suspected to be an alternative for perfluorooctanoic acid (PFOA – CAS 335-67-1), which has been proposed for restriction (Oct 2014) and therefore increasing use and production of alternatives is to be expected.</p> <p>PFOA is used as polymerization aid and is present in the final polymer. Environmental exposure takes place, because of wide dispersive use of the polymer. Furthermore, PFOA is released from manufacturing sites during the production of the respective polymers. Thus, an environmental exposure of ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate may be possible as well.</p> <p>Additionally, the intrinsic properties of the substance may be of concern. The substance is not readily biodegradable. Highest BCF is reported to be 5.8. For the assessment of the bioaccumulation potential additional information (e.g. protein binding potential) may be required, since other mechanisms for bioaccumulation than covered by log K_{ow} and BCF are of relevance for these fluorinated substances.</p>		

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

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Based on a preliminary examination of the available data, information to assess the bioaccumulation potential are required.
 To clarify the bioaccumulation potential a testing on whether the substance binds to proteins would be needed.
 A test on long-term ecotoxicity of the substance might be requested because of so far missing chronic data.

Additionally, a detailed evaluation of the available data may lead to further information requirements.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Depending on the outcome of the substance evaluation, an analysis of risk management options shall be carried out to identify appropriate risk management measures.