Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Ammonium salts of mono- and bis [3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly(substituted alkene)]phosphate
EC Number:	700-403-8
CAS Number:	Not available
Submitted by:	Federal Public Service Health, Food Chain Safety and Environment, Risk Management Service, Belgium
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly(substituted alkene)]phosphate
EC number:	700-403-8
EC name:	
CAS number (in the EC inventory):	Not available.
CAS number:	Not available.
CAS name:	Not available.
IUPAC name:	
Index number in Annex VI of the CLP Regulation	Not available.
Molecular formula:	Not available. as a result of the UVCB character
Molecular weight or molecular weight range:	Not available. as a result of the UVCB character
Synonyms:	-

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

Structural formula:

Not available.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Self classification by the registrant:

According to CLP:

Acute Tox 2;	H330	Fatal if inhaled
Aquatic chronic 3	H412	Harmful to aquatic life with long lasting effects

According to DSD:

T+ ; R26	Very toxic by inhalation
R52/53	May cause long-term adverse effects in the aquatic environment

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☒ (Suspected) PBT	☐ Exposure of sensitive populations	☐ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

Because of a structural similarity many highly fluorinated compounds have raised concern. Perfluorooctanesulphonate (PFOS) has been shown to be persistent, bioaccumulative and toxic. Perfluorinated substances do not occur naturally in the environment, but are produced by man. Substitutes to PFOS can also be potentially harmful.

The substance in question is a perfluorined compound with possible PBT-properties. Although in low tonnage, (1-10 tpa), these type of substances have wide and dispersive uses and both professionals and consumers can come into contact with the substance. For example information on toxicokinetics, adsorption and bioaccumulation could be required.

Waste water treatment plants (WWTP) have been identified as a major source of perfluorocarboxylates (PFCAs) to aqueous environments. One class of commercial surfactants, the polyfluroalkyl phosphates (PAPs) have also been observed in WWTP sludge. A recent study has demonstrated that PAPs biodegrade microbiologically to PFCAs. (H .Lee, J. D'eon, S. Mabury, Environ.Sci.Technol. 2010, 44, 3305-3310).

Of the PFCAs most attention has been given to perfluorooctanoic acid (PFOA) due to its toxic and ecotoxic properties. Recently Norway has made a classification proposal for ammonium salt of PFOA, ammoniumpentadecafluorooctanoate (APFO, CAS 3825-26-1). The proposed classification for human health endpoints is according to CLP: Carc cat 2 (H321), Repro cat 1B, STOT RE1 (H372), STOT RE2 (H373), acute tox Cat 4 (H332 + H302), eye irr cat 2 (H319).

EFSA has recommended in its report (21 February 2008) that studies on toxicokinetics and metabolism of PFOS and PFOA in humans are needed.

3.3 Information on aggregated tonnage and uses

☒ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	☐ Confidential

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System
Both professionals and consumers can use products that contain the substance.			

3.4 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behavior	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	
The test method used to determine biodegradability does not seem to be appropriate for a UVCB substance. Also relevant information on bioaccumulation is not present. These two types of information are necessary to come to an adequate conclusion on the PBT character. Also exposure information is lacking and could be necessary to assess the risk for the environment.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
If the PBT/vPvB character of the substance is confirmed, possibly identification as a PBT and SVHC.			