

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt
Chemical Group:	
EC Number:	700-161-3
CAS Number:	to be determined
Submitted by:	NL-CA
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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 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt
EC number:	700-161-3
EC name:	-
CAS number (in the EC inventory):	-
CAS number:	To be determined
CAS name:	-
IUPAC name:	
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	This is a multi-constituent substance. No molecular formula is available.
Molecular weight or molecular weight range:	This is a multi-constituent substance. No molecular weight range is available.
Synonyms:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

N.A.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

CLP criteria:

Acute Tox. 1, H330: Fatal if inhaled.

STOT Single Exp. 3, H335: May cause respiratory irritation.

STOT Rep. Exp. 2, H373: May cause damage to liver through prolonged or repeated exposure

Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects. M-factor = 10

CLP criteria:

T+; R26 Very toxic; Very toxic by inhalation.

Xn; R48/22 Harmful; Harmful: danger of serious damage to health by prolonged exposure if swallowed.

N; R51/53 Dangerous for the environment; Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Remarks C&L: C&L is based on reference substance, but the toxicity information is gathered on the product as sold.

Other Remarks: Read across is applied.

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

<input type="checkbox"/> (Suspected) CMR	<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input checked="" type="checkbox"/> (Suspected) PBT/vPvB	<input type="checkbox"/> Exposure of sensitive populations	<input type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

Biodegradation in water

Screening: Read across of one substance to registered substance. The registrant concludes that registered substance is not Ready Biodegradable based on the results of an inherent biodegradation test conducted on read across substance. The inherent biodegradation test showed that the read across substance undergoes primary biodegradation but is not ultimately biodegradable. The formation of fluorinated degradation products, which are expected to be long-lived, was also observed during the study.

Stability: The read across substance was hydrolytically stable (half-life > 1 year) at environmentally relevant pHs. Accordingly, due to the same phosphate functionality, registered substance would also be expected to be hydrolytically stable.

Bioaccumulation

Experimental Log Kow values are as follows: mono species: -1.37, bis species: 0.35 and pyro species: 0.20. No test data on bioaccumulation are available. Perfluorinated UVCB compound with concern based on lack of information on its bioaccumulation properties. Bioaccumulation study is not normally required at this tonnage level (10-100 tpa). Missing information is linked to incomplete PBT and vPvB assessment of the substance. The request seems reasonable given that other PFOS and other PFOS related substances are considered PBT substances.

Toxicity

Fish

Short term: *Pimephales promelas*, LC₅₀, (96-h) >120 mg/L; Long-term: (Read-across applied to registered substance) NOEC (90-d) 2.5 mg/L.

Aquatic invertebrates

Short-term: *Daphnia magna* EC₅₀ (48-h) 6.2 mg/L (based on nominal concentrations and immobility)

Long-term: *Daphnia magna* NOEC (21-d) 0.409 mg/L (mean measured based on immobilization).

Algae

Pseudokirchneriella subcapitata, 72-h ErC₅₀ was >120 mg/L and NOEC of 120 mg/L.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 – 10 tpa	<input 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 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input checked="" type="checkbox"/> Confidential			
<input type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
No data			

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check final	<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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
No data	

3.5 Information to be requested to clarify the suspected risk

<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 type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>Additional information on persistence of the degradation products may be requested, depending on the outcome of the persistence evaluation.</p> <p>Bioaccumulation study. The request seems reasonable given that other PFOS and other PFOS related substances are considered PBT substances.</p> <p>Additional information on chronic toxicity may be requested, depending on the outcome of the evaluation of the read-across arguments on toxicity.</p>	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
If confirmed to be a PBT/vPvB substance, identification as SVHC.			