Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	bis(nonafluorobutyl)phosphinic acid
Chemical Group:	
EC Number:	700-183-3
CAS Number:	52299-25-9
Submitted by:	Germany
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	.3
	1.1 Other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING 2.1 Harmonised Classification in Annex VI of the CLP 2.2 Self classification 2.3 Proposal for Harmonised Classification in Annex VI of the CLP	.4 4 4 4
3	INFORMATION ON AGGREGATED TONNAGE AND USES	.4
	OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT JITABILITY FOR SUBSTANCE EVALUATION	.4
5	 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE 5.1 Legal basis for the proposal 5.2 Selection criteria met (why the substance qualifies for being in CoRAP) 5.3 Initial grounds for concern to be clarified under Substance Evaluation 5.4 Preliminary indication of information that may need to be requested to clarify the concern 5.5 Potential follow-up and link to risk management 	.5 5 5 6 6

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	
IUPAC name:	bis(nonafluorobutyl)phosphinic acid
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_8F_{18}PO_2H$
Molecular weight or molecular weight range:	502.038 g·mol⁻¹
Synonyms/Trade names:	4:2diPFPA

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. 3	H301
Eye Damage 1	H318

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

There is no notificaions to the 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					
🖾 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 - 10,000,00	0 tpa	🗌 10,000,000 - 100,000,000 tpa		□ > 100,000,000 tpa	
□ <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa) □ Confidential			idential		
🛛 Industrial use	Professional use [Consumer use		Closed System
The substance is used in industrial and professional settings, e.g. during mixing or blending in batch processes during formulation or preparation of articles, and roller application or brushing.					

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)	

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
- Sulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- \Box Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- I Fulfils exposure criteria
- □ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns			
CMR	Suspected CMR^1 $\Box C \Box M \Box R$	Potential endocrine disruptor	
Sensitiser	Suspected Sensitiser ¹		
PBT/vPvB	Suspected PBT/vPvB ¹	igtimes Other (please specify below)	
Exposure/risk based concerns			
U 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)	

<u>CMR/Sensitiser</u>: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory) <u>Suspected CMR/Suspected sensitiser</u>: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classified according to CL

properties/suspected sensitising properties (not classified according to CLP harmonized or registrant selfclassification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Bis(nonafluorobutyl)phosphinic acid (4:2 diPFPA) is an alternative for PFOA related substances, which have been proposed for restriction (Oct 2014) and therefore increasing use and production of alternatives is expected. Thus, environmental exposure might increase in the future.

The intrinsic properties of 4:2 diPFPA may be of concern. 4:2 diPFPA is stated to be not readily biodegradable. Nevertheless, it is expected that perfluorobutanoic acid (PFBA) will be the final degradation product. No information on bioaccumulation and chronic toxicity are available. For the assessment of the bioaccumulation potential additional information (e.g. protein binding potential) may be required, since other mechanisms for bioaccumulation than log Kow and BCF are of relevance for these per- and polyfluorinated substances.

In addition PFBA is expected to have a high mobility in the environment, which also needs to be assessed, e.g. in terms of its potential for long-range transport.

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
$oxedsymbol{\boxtimes}$ Information on fate and behaviour	imes Information on exposure
Information on ecotoxicological properties	Information on uses
Information ED potential	Other (provide further details below)

Uses, exposure, toxicological properties and ED potential where not target in the manual screening but might be part of the substance evaluation.

Based on a preliminary examination of the available data, information to assess the bioaccumulation potential and the ecotoxicity are required.

In detail, a test on long-term ecotoxicity of 4:2 diPFPA 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

Harmonised C&L	Restriction	Authorisation	Other (provide further details)	
Depending on the outcome of the substance evaluation, an analysis of Risk Management Options shall be carried out to identify appropriate risk management measures.				