

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Reaction products of bis(4-methylpentan-2-yl)dithiophosphoric acid with phosphorus oxide, propylene oxide and amines, C12-14-alkyl (branched)
Chemical Group:	UVCB
EC Number:	931-384-6
CAS Number:	NS
Submitted by:	Slovenia
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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

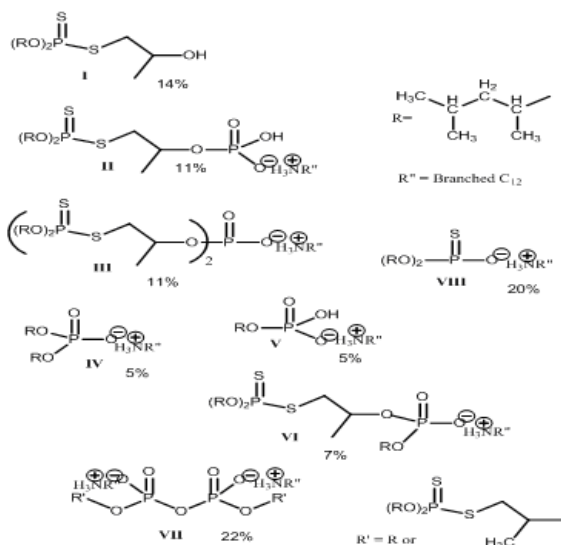
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Reaction products of bis(4-methylpentan-2-yl)dithiophosphoric acid with phosphorus oxide, propylene oxide and amines, C12-14-alkyl (branched)
EC number:	931-384-6
EC name:	
CAS number (in the EC inventory):	
CAS number:	
CAS name:	
IUPAC name:	Reaction products of bis(4-methylpentan-2-yl)dithiophosphoric acid with phosphorus oxide, propylene oxide and amines, C12-14-alkyl (branched)
Index number in Annex VI of the CLP Regulation	Not applicable.
Molecular formula:	Too complex
Molecular weight or molecular weight range:	181.1-773.3
Synonyms:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not classified.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Included in the registration data:

CLP

Flam. Liquid 3 H226: Flammable liquid and vapour.

Acute Tox. 4 H302: Harmful if swallowed.

Eye Damage 1 H318: Causes serious eye damage
(specific concentration limits: > 50 %)

Skin Sens. 1 H317: May cause an allergic skin reaction.

Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects.

DSD

Xn; R22 Harmful; Harmful if swallowed

Xi; R41 Irritant; Risk of serious damage to eyes (specific concentration limits > 50 %)

R43 May cause sensitisation by skin contact,

N; R51/53 Dangerous for the environment; Toxic to aquatic organisms, may cause longterm adverse effects in the aquatic environment)

There are no notifications to the Classification and Labelling Inventory for this substance.

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

The substance is a suspected PBT/vPvB and there is consumer use in lubricants and greases.

Molecular formula of this organic UVCB substance is not specified. Substance is a complex reaction mixture with variable composition which leads to difficulties in substance identification and wide variation in given phys-chem parameters.

Substance has a low vapour pressure (0.032 Pa at 25 °C).
 Water solubility is reported to be loading dependent

- 39.5 mg/L at loading rate 100 mg/L
- 138 mg/l at loading rate 1000 mg/L

Partitioning coefficient log Pow ranges from < 0.3 to > 7.10 (OECD 117) of which 59% between log Pow 1.81- 6.
 Reported Log Koc values ranged from < 1.25 to 5.09 (EU Method C.19 but outside the calibration standards)

The substance is potentially PB(T). Evaluation of T depends on the approach taken with WAF concentrations. Registrant suggests that the substance is potentially P but not B or T.

- UVCB substance identity should be clarified
- Simulation test on biodegradability in soil would confirm P
- Read across approach on bioaccumulation studies should be looked more closely
- Using WAF concentration in T assessment leads to uncertainty

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 checked="" 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 type="checkbox"/> Confidential			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System

Substance is used as lubricant additive and lubricants

- Workers: (lubricant additives, lubricants and greases); PROC 10, 13, 15,
- Professional workers: PROC 10, 11, ERC 8a,b, 9a,b,
- Consumers; General consumer use of lubricants and greases in vehicles or machinery, Consumer use in open system: application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat). ERC 8ab, 9ab (wide and dispersive indoor/outdoor use closed and open systems)
- Member; Workers PROC 10, 13, 15; Professional PROC 10, 11; Consumer use in closed/open systems ERC 9 a,b and 8a,d.

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

<input type="checkbox"/> Compliance check	<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)	

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>Clarification of the substance identity; refine phys-chem parameters.</p> <p>Persistency; Simulation tests in soil could be considered</p> <p>Bioaccumulation; bioaccumulation potential estimation should be refined. Possibility to ask for test with registered substance or justification/analysis of the potential read across substances.</p> <p>Toxicity; Find a solution on how to use or interpret WAF based ecotoxicity results in relation to PBT assessment and PNEC derivation.</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 type="checkbox"/> Other (provide further details)
Potential SVHC			