Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate
Chemical Group:	dithiophosphate
EC Number:	401-850-9
CAS Number:	255881-94-8
Submitted by:	BE CA
Published:	26/03/2014

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate
IUPAC name:	S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O'-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate
Index number in Annex VI of the CLP Regulation	015-146-00-0
Molecular formula:	
Molecular weight or molecular weight range:	346.5 – 486.8 g/mol
Synonyms/Trade names:	Trade names : Hi-TEC 511 Performance Additive, X-4261

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

Structural formula:

Not disseminated

1.2 Similar substances/grouping possibilities

n.a.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Aquatic Acute 1 ; H400: Very toxic to aquatic life
Aquatic Chronic 1 ; H410: Very toxic to aquatic life with long lasting effects

2.2 Self classification

- In the registration

  Same as the harmonised

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

  Eye Irrit. 2 ; H319: Causes serious eye irritation

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

n.a.

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 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☒ Confidential
There is one NONS registration with confidential tonnage. In addition are there 1 joint and 4 individual registrations all with tonnage bands of 10-100 tpa.		

☒ *Industrial use*	☒ Professional use	☐ Consumer use	☐ Closed System
Industrial use: confidential Professional use: confidential Service life: confidential			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☐ Article 44(2) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

4.2 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

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	Suspected Sensitiser[1]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure / risk based concerns		
☒ 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)

[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

Based on the currently available data, it is concluded that various constituents of this UVCB substance probably meet the definitive PBT criteria. The UVCB character of the substance hampers a clear unambiguous conclusion and this uncertainty can be resolved by a targeted test proposal. The following observations can be made in relation to the relevant PBT characteristics.

Persistency:

Abiotic degradation does not take place to a relevant extent.

The results of the available experimental tests indicate that the substance is not readily biodegradable. A QSAR and a read-across approach suggest that various constituents are persistent. No conclusive statement can be presented in relation to the definitive P-criterion.

Bioaccumulation:

Based on an experimental BCF-test some constituents meet the definitive B-criterion.

Toxicity:

A test with the substance points out that the definitive T-criterion for freshwater organisms is met.

Exposure of the environment:

In view of the described uses, relevant exposure of the soil compartment is to be foreseen.

4.4 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)	

Information presented in the framework of Dir. 67/548 did not take away the uncertainties in relation to the suspected PBT-character of various constituents.

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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☒ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

Mainly information concerning the P-characteristics of various constituents is necessary to clarify the concern. However also additional data concerning the B, T and exposure characteristics could be appropriate as well.

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)

Depending on the outcome of the evaluation any of the above mentioned RMMs could be initiated if warranted.