Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Bis(isopropyl)naphthalene
Chemical Group:	
EC Number:	254-052-6
CAS Number:	38640-62-9
Submitted by:	Swedish Chemicals Agency, Sweden
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

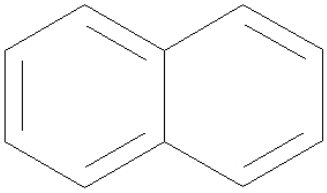
1.1 Name and other identifiers of the substance

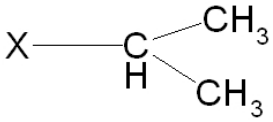
Table 1: Substance identity

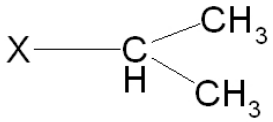
Public Name:	Bis(isopropyl)naphthalene
EC number:	254-052-6
EC name:	Bis(isopropyl)naphthalene
CAS number (in the EC inventory):	38640-62-9
CAS number:	38640-62-9
CAS name:	Naphtalene,bis(1methylethyl)-
IUPAC name:	Bis(isopropyl)naphthalene
Index number in Annex VI of the CLP Regulation	Not applicable.
Molecular formula:	C16H20
Molecular weight or molecular weight range:	212.33
Synonyms:	Diisopropylnaphtalene DIPN KMC-113, Ruetasolv DI, Ruetasolv SD 1000, Ruetasolv KX 1000, Ruetaflex 1000, SOLVENTE KMC 113, KMC

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

Structural formula:







Mixture consisting of seven isomers of which some are monoalkylated at both rings and some dialkylated at one ring.

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

The registration dossier includes the following self classification.

According to CLP:

Asp.tox 1, H304: May be fatal if swallowed and enters airways

Aquatic chronic 4, H413: May cause long lasting harmful effects to aquatic life.

According to DSD:

R53: May cause long-term adverse effects in the aquatic environment.

In addition are the following classification(s) included in the Classification and Labelling Inventory:

Acute Tox.3, H331: Toxic if inhaled

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

Skin irrit.2, H315: Causes skin irritation.

Eye irrit. 2, H319: Causes serious eye irritation.

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/vPvB	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

Bis(isopropyl)naphthalene (DIPN) is suspected to meet the PBT/vPvB criteria of Annex XIII in REACH.

DIPN was one of the substances that were assessed by the former TCNES PBT working group. It was not possible for the PBT WG to come to a final conclusion mainly because the available data on degradability did not allow for a definite conclusion on the persistency of DIPN. The data on degradability were conflicting with some screening studies indicating slow degradation while other seemingly more reliable screening studies indicated that DIPN is ready biodegradable. However, the test substance used was not defined and thus the relevance of the results could not be assessed. Therefore further biodegradation testing with the substance as produced was required in COMMISSION REGULATION (EC) No 465/2008 to confirm or refute the indicated ready biodegradability.
The requested study has been performed but the results do not confirm DIPN being ready biodegradable. On the contrary, the results indicate that at least some of the isomers may meet the P or vP criterion.

The substance meets the B-criterion and two of the seven isomers may meet the vB criterion as well. However, it is not possible from the available studies to identify which isomer has which BCF, as the results for the seven isomers are given as a BCF for each peak in the chromatogram and the peaks are not identified.

Having a NOEC of 0.013 mg/l (Daphnia magna 21 d) the toxicity of DIPN is on the borderline of meeting the T-criterion of 0.01 mg/l. We do however, have doubts about the reliability of the study as the NOEC is based on nominal concentrations and no analytical monitoring was performed. The fact that there have been problems with maintaining test concentrations in most of the other available aquatic toxicity studies gives us reason to believe that the toxicity of DIPN may be underestimated. For this reason the former PBT WG concluded that the T-criterion was fulfilled. The registrant on the other hand, draws the conclusion that the study is valid and that DIPN does not meet the T-criterion.

DIPN has a wide dispersive use and is used in e.g. carbonless copy paper, coatings, colours, lacquers, inks, adhesives and sealants.

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		

Please provide further details

☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Closed System
DIPN has a wide range of uses. It is used among other things in sealants, adhesives, carbonless copy paper, heat transfer fluids, coatings and paints, thinners, paint removes, fillers, putties, plasters, and modeling clay. DIPN has a wide dispersive indoor as well as outdoor use.			

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

☐ Compliance check	☐ 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)	
Please provide further details	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	
Further information on the persistency of DIPN is needed, presumably a simulation study on degradation in surface water, soil or sediment. Since there are indications from the available studies that at least two of the isomers (not identified) fulfill the vB criterion, studies on bioaccumulation may also be needed. Finally, further ecotoxicity studies may also be necessary to either confirm or refute that DIPN meets the T-criterion.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☒ Authorisation	☐ Other (provide further details)
If DIPN is identified as meeting the PBT/vPvB criteria we will consider proposing it for inclusion in the Candidate List.			