Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	3a,4,7,7a-tetrahydro-4,7-methanoindene
Chemical Group:	organic
EC Number:	201-052-9
CAS Number:	77-73-6
Submitted by:	France
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

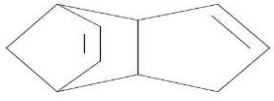
1.1 Other identifiers of the substance

Table 1: Substance identity

EC Number:	201-052-9
CAS Number:	77-73-6
EC name:	3a,4,7,7a-tetrahydro-4,7-methanoindene
IUPAC name:	3a,4,7,7a-tetrahydro-4,7-methanoindene
Index number in Annex VI of the CLP Regulation	601-044-00-9
Molecular formula:	$C_{10}H_{12}$
Molecular weight or molecular weight range:	132
Synonyms/Trade names:	*Dicyclopentadiene*

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Harmonised classification Index n°601-044-00-9	**Additional/diverging self-classifications from C&L inventory**
Flam Liq 2 – H225 Acute Tox 4 – H302 (oral) Acute Tox 4 – H332 (inhalation) Skin Irrit 2 – H315 Eye Irrit 2 – H319 STOT SE 3 – H335 Aquatic Chronic 2 – H411	

2.2 Self classification

- In the registration
  - Flam Liq 3; H226: Highly flammable liquid and vapour.
  - Acute Tox 2; H330 (inhalation): Fatal if inhaled.
  - Acute Tox 3 – H331 (inhalation): May cause respiratory irritation.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Asp. Tox. 1; H304: may be fatal if swallowed and enters airways.

No current intention or proposal for revision of harmonised classification.

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

High tonnage			
☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System

The main uses described relate to the manufacture of the substance and its use in resins.

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)	
None identified.	

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

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☐ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 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)
Developmental toxicity is investigated in several multi-generation and prenatal developmental toxicity studies. Adverse developmental effects are reported at high doses. 3a,4,7,7a-tetrahydro-4,7-methanoindene is produced and used in a high tonnage. For several exposure scenario high RCR are obtained whereas it is noted that assessment factor may be underestimated as they are not consistent with REACH guidance.		

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
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☒ Other (provide further details below)
It is noted that the multi-generational studies and prenatal developmental studies that raise the developmental toxicity concern are poorly reported in the registration dossier. A more in depth description of the study design and the results should greatly help to assess the validity of the studies and the relevance of the effects in the evaluation process.	

[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

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☒ Restriction	☐ Authorisation	☐ Other (provide further details)
Follow-up to be decided further to evaluation.			