Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Thiram
Chemical Group:	
EC Number:	205-286-2
CAS Number:	137-26-8
Submitted by:	Swedish Chemicals Agency
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

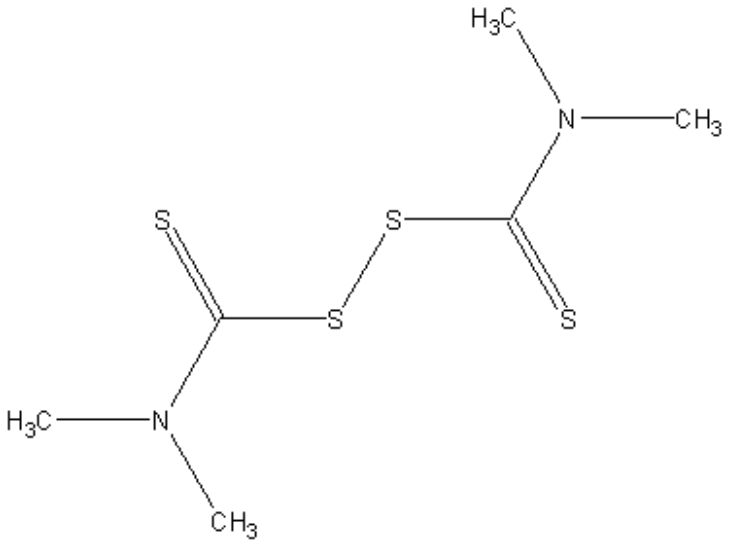
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Thiram
EC number:	205-286-2
EC name:	Thiram
CAS number (in the EC inventory):	137-26-8
CAS number:	137-26-8
CAS name:	tetramethylthioperoxydicarbonic diamide
IUPAC name:	tetramethylthiuram disulfide
Index number in Annex VI of the CLP Regulation	006-005-00-4
Molecular formula:	C6H12N2S4
Molecular weight or molecular weight range:	240.4
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

CLP 1272/2008 Appendix VI table 3.1

Acute Tox. 4; H332: Harmful if inhaled.

Acute Tox. 4: H302: Harmful if swallowed; H332: Harmful if inhaled.

Skin Irrit. 2 : H315: Causes skin irritation.

Eye Irrit. 2: H319: Causes serious eye irritation.

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

STOT Rep. Exp. 2: H373: May cause damage to liver through prolonged or repeated exposure via oral route.

Aquatic Acute 1 H400: Very toxic to aquatic life

Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
M=10

67/548/EEC Annex 1 Index number 006-005-00-4

Xn; R20/22 Harmful; Harmful by inhalation and if swallowed.

Xn; R48/22 Harmful; Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Xi; R36/38 Irritant; Irritating to eyes and skin.

R43: May cause sensitisation by skin contact.

N; R50/53 Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

None.

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

Information from databases:

EC Endocrine Substances Database	Conclusion: Clear Evidenc of ED effects Human Health: CAT1 Wildlife CAT3
QSAR toolbox profiler ERBA	NO ER Binding Alert
Predicted ERBA TIMES	
FDA Endocrine Screening Database	Non Potential Endocrine Disrupter via ER Gene/Species:/Structure:Phyto/Assay: ER Gene (Reporter Gene Assay)

The substance is used in rubber articles; it is also used in pesticides.

For some IND PROCs the combined RCR is close to 1.

Repeated dose toxicity studies in multiple species. LOAEL 90 day rat 38 mg/kg/day (reduced body weight and effects on clinical chemistry); LOAEL 1 yr dog 2.6/7.2 mg/kg/day (M/F). Indication of liver effects and some literature information on testicular dysfunction are reported. Reproductive toxicity: A comparison between the severity of the maternal toxicity and the severity of the findings in the offspring must be performed. Severe malformations in the fetus even at marked maternal toxicity should not be dismissed for classification. Developmental toxicity: The dossier contains developmental toxicity studies in both rat and rabbit. In the rat study, maternal LOAEL is reported as 7.5 mg/kg/day (based on marginally, not statistically significant, reduced body weight) and fetal LOAEL as 30 mg/kg/day (based on statistically significant reduction in pup weight). There is a dose response relationship in the reduced body/pup weight. In the rabbit study, poorly reported but LOAEL for maternal toxicity and NOAEL for teratogenicity is both ca. 5 mg/kg/day according to the registrant. Fertility: The two generation study is poorly reported (NOAEL for parental systemic toxicity 1.5 mg/kg/day for F1a and 3 mg/kg/day for all subsequent ones. The NOAEL for neonatal toxicity is derived at 3 mg/kg/day whereas the NOAEL for reproductive toxicity was equal to or greater than 9 mg/kg/day)

EC Endocrine Substances Database: Conclusion: Clear Evidence of ED effects Human Health: CAT1 Wildlife CAT3. Further examination of the information on which the conclusion in the EC list is based is needed.

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
Please provide further details			

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)	
The substance is under Review as a Biocidal active substance, it is needed to consider if information and evaluation on ED could already take place under the BPD.	

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)	
To examine the basis of the EC List conclusion for potential evidence of ED. Clarification on the possible reduction of the human exposure where the RCRs are close to 1.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☐ Authorisation	☒ Other (provide further details)
New classification, new risk management measures to limit exposure. Possible refinement of the RCR and in consequence the risk reduction measures.			