



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione
EC Number:	258-904-8
CAS Number:	53988-10-6
Authority:	DE MSCA
Date:	22/03/2016

Note

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

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	4
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	5
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	6
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	8
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione
IUPAC name (public):	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₈ H ₈ N ₂ S
Molecular weight or molecular weight range:	164.2 g/mol
Synonyms:	Vulkanox MB2/MG

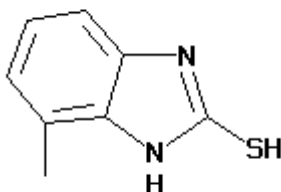
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" type="checkbox"/> Testing proposal (EC 262-872-0)
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII ¹
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	

¹ Please specify the relevant entry.

Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)
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TPE on reproductive toxicity (pre-natal developmental toxicity) testing is proposed with the substance 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (CAS: 61617-00-3, EC: 262-872-0).

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration:
Acute Tox. 4 H302, Acute Tox. 4 H332, Repr. 2 H361 (Oral), STOT RE 2 H373 (Oral), Aquatic Chronic 1 H410 M-factor = 1
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Aquatic Chronic 3 H412

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
Joint Submission.		

4.2 Overview of uses

The uses of the substance indicate a probable release of relevant amounts of the substance into the environment. There are article service life uses with wide dispersive outdoor use.

Table: Uses.

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Uses as intermediate	-
Formulation	
Uses at industrial sites	Production of tyres, rubber and plastic goods. Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers.
Uses by professional workers	

² Data taken from ECHA dissemination site (accessed in May 2015)

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

Consumer Uses	
Article service life	Production of tyres, rubber and plastic goods. Environmental exposure may be expected during article service life. AC 1: Vehicles AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 3: Electrical batteries and accumulators AC 10: Rubber articles AC 13: Plastic articles
Use advised against	

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

³ 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

ED concern:

The substance gives evidence for being an endocrine disruptor for the environment. Because of structural characteristics the substances can interact with the hypothalamus-pituitary-thyroid axis, since they also belong to the group of thioamides where most of the thyroid disruptors are found (e.g. Methimazole, Phenylthiourea, Propylthiouracil, Mercaptoimidazole). This group of chemicals interacts on the one hand with the thyroid-peroxidase-enzyme (which has an important role in the thyroid hormonesynthesis) and on the other it can block the deiodinase-enzyme (which is in charge for the conversion of T4 to T3). It is not yet clearly proven, if these substances really cause such effects.

According to the publications of (Kawasaki et al., 1998; Sakemi et al., 2002) the substance has a lower thyroid disruption potential than MBI (a clear thyroid disruptor). (Kawasaki et al., 1998; Sakemi et al., 2002) conducted an in vitro test (lactoperoxidase-LPX assay) and a two-week repeated oral administration toxicity study with male rats. There is a clear hint from the papers that the substance is thyroid active.

The substance is not readily biodegradable, indicating that it has the potential to persist in the environment. There is no test on bioaccumulation (in the registration dossier) available. The log K_{ow} is 0.3 to 0.4 according to the registration dossier.

Due to the registered uses of the substance which point towards a wide dispersive use, significant environmental exposure has to be assumed. Therefore, the potential risk of endocrine disruptive properties in the environment has to be clarified.

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

It is necessary to examine the endocrine disrupting properties of the substance and the effects on the environment. For this reason information from a non-standard ED-relevant test might be required as there is no in vivo study available to conclude for the environment on the apical effects on organisms.

An Amphibian metamorphosis assay (AMA – OECD 231) (Tier 1), a Larval Amphibian Growth and Development Assay (LAGDA) (Tier 2) or another test might be suitable to provide the required information.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details) (ED-concern)
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If the ED-concern is substantiated a SVHC-identification according to art. 57 f might be proposed and an analysis of risk management options would be undertaken to identify the most adequate regulatory action.

References:

Kawasaki, Y., Umemura, T., Saito, M., Momma, J., Matsushima, Y., Sekiguchi, H., Matsumoto, M., Sakemi, K., Isama, K., Inoue, T., Kurokawa, Y., Tsuda, M., 1998. Toxicity study of a rubber antioxidant, 2-mercaptobenzimidazole, by repeated oral administration to rats. *The Journal of toxicological sciences* 23, 53-68.

Sakemi, K., Ito, R., Umemura, T., Ohno, Y., Tsuda, M., 2002. Comparative toxicokinetic/toxicodynamic study of rubber antioxidants, 2-mercaptobenzimidazole and its methyl substituted derivatives, by repeated oral administration in rats. *Arch Toxicol* 76, 682-691.