baua:
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, zinc salt
EC Number:	262-872-0
CAS Number:	61617-00-3
Authority:	DE MSCA
Date:	22/03/2016

Note

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

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1 IDENTITY OF THE SUBSTANCE

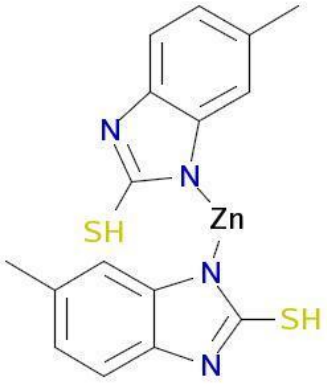
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt
IUPAC name (public):	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C8H8N2S.1/2Zn
Molecular weight or molecular weight range:	391.8 g/mol
Synonyms:	

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

Structural formula: This structural furmula represents one of the possible structures.



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal [TPE on reproductive toxicity (pre-natal developmental toxicity)]
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
Harmoni sed C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	

[1] Please specify the relevant entry.

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

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, Skin Sens. 1B H317, Acute Tox. 4 H332, Repr. 2 H361 (Oral), STOT RE 2 H373 (Oral), Aquatic Chronic 1 H410 M-factor = 10

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

  Aquatic Chronic 2

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 USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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
Joint Submission.		

4.2 Overview of uses

The uses of 2-MMBI 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:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

Part 2:

	Use(s)
Formulation	Refer the dissemination site
Uses at industrial sites	Refer the dissemination site
Uses by professional workers	Refer the dissemination site
Consumer Uses	Consumer handling of rubber and plastic goods.

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

Article service life	Consumer handling of 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 ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☒ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ 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)

[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 fould (e.g. Methimazole, Phenylthiourea, Propylthiouracil, Mercaptoimidazole). This group of chemicals interacts on the one hand with the thyoroid-peroxidase-enzym (which has an important role in the thyroid hormonsynthesis) and on the other it can block the deiodinase-enzym (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 MMBI is thyroid active.

The substance is not readily biodegradable, indicating that it has the potential to persist in the environment.

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 t 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 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 would be necessary to provide the required information.

5.5 Potential follow-up and link to risk management

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

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.