Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**bis(dibutyldithiocarbamato-S, S') copper**
EC Number:	**237-695-7**
CAS Number:	**13927-71-4**
Authority:	**FR MSCA**
Date:	**22/03/2016**

Note

This document has been prepared by the evaluating Member State(s) given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

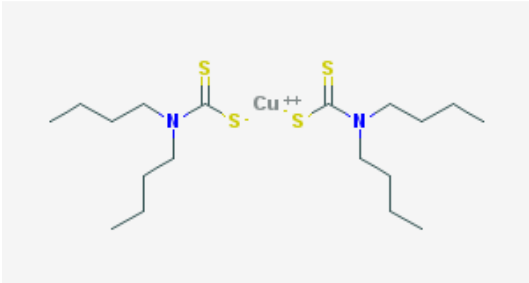
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	bis(dibutyldithiocarbamato-S, S') copper
IUPAC name (public):	bis(dibutyldithiocarbamato-S,S')copper
Index number in Annex VI of the CLP Regulation:	Not applicable
Molecular formula:	$C_{18}H_{36}CuN_2S_4$
Molecular weight or molecular weight range:	472 g/mol
Synonyms:	CDBC

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

Structural formula:



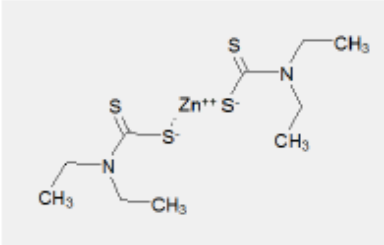
1.2 Similar substances/grouping possibilities

Table 2: Similar substances

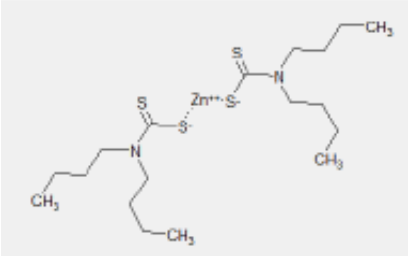
Name	CAS No	EC No	Comments
Zinc diethyldithiocarbamate; ZDEC	14324-55-1	238-270-9	Registered, Annex VI of CLP regulation
Zinc di-n-butyldithiocarbamate; ZDBC	136-23-2	205-232-8	Registered, Annex VI of CLP regulation
Ziram	137-30-4	205-288-3	Registered, ongoing SEV by DK, Annex VI of CLP regulation, RMOA under development (Scope: ED) by DK, Approved in regulation (EU) no 540/2011

Structural formula:

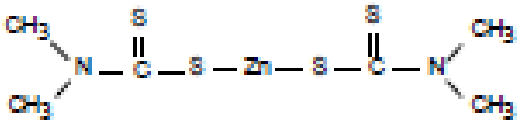
ZDEC:



ZDBC:



Ziram:



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
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV

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

The registration data contains a decision on a testing proposal for CDBC (CAS 13927-71-4, decision number TPED-D-2114292058—44-01/F) "OECD Guideline 211 (Long-term aquatic toxicity study on Daphnia)", "OECD Guideline 225 (Sediment-Water Lumbricus Toxicity Test Using Spiked Sediment)", "OECD Guideline 222 (Long-term toxicity test on macroorganisms)". Further, a growth test with terrestrial plants (OECD 208) and a nitrogen transformation test (OECD 216) were requested. The deadline for submission of this information in 02/02/2017.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Not included in Annex VI of CLP Regulation (Regulation (EC) 1272/2008).

3.1.2 Self classification

- In the registration:

  Aquatic Chronic. 4, H413 - May cause long lasting harmful effects to aquatic life.

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

  Skin Sens. 1, H317 – May cause an allergic skin reaction

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table 3: 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

Table 4: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	Production of acrylic acid and its derivatives
Uses at industrial sites	Production of acrylic acid and its derivatives

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)

[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

Suspected reproductive toxicity

With regard to the reproductive toxicity endpoint, a developmental toxicity screening test has been conducted according to OECD test guideline 421. In this study, decreased survival (PND 0-4) has been observed.

No further reproductive or developmental toxicity tests have been performed. A read-across with ZDEC has been proposed for developmental toxicity (published data in japanese, only abstract available). The developmental and reproductive effects observed with other dithiocarbamate (e.g. Thiram) raise concern that the substance is a reproductive/developmental toxicant, which need to be clarified.

Potential endocrine disruptor

Ziram is currently under RMOA and hazard evaluation for ED properties. For ZDEC and ZDBC a read-across with Ziram is proposed for the reproductive endpoint in the ECHA disseminated website. Moreover, qHTS[2] on ZDBC give positive results for Thyroid hormone receptor and ER receptor. For CDBC, a read-across with ZDEC and ZDEC has been proposed by the registrant for some endpoints (e.g short-term toxicity). Therefore, the endocrine disruptor potential of CDBC need to be clarified.

Suspected PBT/vPvB

Regarding persistence, CDBC is considered as non readily biodegradable (OECD 301F). Aquatic bioaccumulation of CDBC was estimated by QSAR and no data are available in terrestrial compartment. As only data on algae are available for ecotoxicity of CDBC, data on aquatic, sediment and terrestrial toxicity are lacking. Following dossier evaluation of CDBC, a testing proposal (TPE-D-2114292058-44-01/F) on ecotoxicity of CDBC is currently in progress (decision date 26/01/15) concerning Long-term aquatic toxicity study on Daphnia (OECD 211), Sediment-Water Lumbricus Toxicity Test using Spiked Sediment (OECD 225), Long term toxicity test on macroorganisms (OECD 222), Terrestrial plants, growth test (OECD 208) and Effects on soil micro-organisms (OECD 216).

The registrant shall submit to ECHA by 2 February 2017 an update of registration dossier containing the information required by the testing proposal and an update of the Chemical Safety Report. This data will clarify the T criteria. Then, during substance evaluation, supplemental informations on behaviour of CDBC (abiotic degradation) and bioaccumulation will be needed.

No risk assessment has been performed in the registration dossier, but it is indicated that due to its properties the substance should not be release in the environment. The hazards for both human health and environment and the risk assessment have to be assessed for this substance.

[2] Quantitative High Througput Screening

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)
During the substance evaluation it should be verified if the proposed read-across with ZDEC, ZDBC and ziram are relevant. Furthermore, the reproductive/developmental toxicity and ED concerns of CDBC should be clarified. Regarding Environmental Hazard, persistence (especially abiotic degradation), bioaccumulation and ecotoxicity data of CDBC are lacking and they should be clarified by further analyses. As a testing proposal on ecotoxicity of CDBC is currently in progress and the data are needed for substance evaluation, evaluation should be performed not sooner than 2018. Moreover, at this time, the ongoing assessment on Thiram will be more mature, enabling proper read-across.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Potential follow-up actions for the substance depend on the outcome of this substance evaluation. RMOA for PBT/vPvB and ED properties or harmonized C&L for reproductive/developmental toxicity concerns may be considered.			