EUROPEAN CHEMICALS AGENCY

Helsinki, 21 March 2018

Addressee: [redacted]

Decision number: TPE-D-2114394604-42-01/F
Substance name: Bis(dibutyldithiocarbamato-S,S')copper
EC number: 237-695-7
CAS number: 13927-71-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 23/08/2017
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation.

To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **28 June 2019**. You also have to update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)**

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on fish Fish, early-life stage toxicity test, OECD TG 210 with the following justification: *"Two long-term toxicity studies are already available for invertebrates (OECD 211) and algae (OECD 201). Since no adverse effect was observed in any of these tests, the chemical safety assessment indicates the need to further investigate the risk for the pelagic aquatic compartment. Fish is the only remaining trophic level considered under REACH and for which long-term toxicity testing has not been assessed. No datum for long-term toxicity to fish is available. At now, there is no evidence that fish could be expected to be less sensitive than invertebrates and/or algae on the long-term. In addition, fish long-term toxicity testing is a standard information requirement under annex IX of REACh regulation EC 1907/2006. Therefore, an OECD 210 is proposed as a last resort and cannot be waived."* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

ECHA notes that no information on toxicity to fish is available in the registration dossier. ECHA further notes that due to the low water solubility of the registered substance, the short-term data cannot serve as a compelling evidence to predict relative differences in species sensitivity. For this reason, the aquatic Integrated Testing Stratergy (ITS) outlined in the *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3., is not applicable and the long-term testing on both invertebrates and fish are to be conducted. ECHA points out that you have already provided information in relation to long-term toxicity to aquatic invertebrates.

ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity testing on fish. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD TG 210).

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s). In addition, you should make every effort to quantify the concentrations of the substance during the test as specificed in the section "Frequency of analytical Determinations and Measurements" of the OECD TG 210. If Water Accommodated Fraction (WAF) method is used, the method to prepare the WAF should be fully described in the test report and robust chemical analysis should be provided.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 15 months. You sought to justify this request by low water solubility (around 1 µg/L) of the substance and analytical challenges. In your comments you state that due to properties of the registered substance and related analytical challenges you would conduct the test with radiolabelled material. You consider that time to complete radiolabelling would take minimum of 3 months. ECHA considers the requested 3 months extension of the deadline feasible to complete the study using the readiolabelled test material. Therefore, ECHA has granted the request and set the deadline to 15 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 31 March 2017.

ECHA held a third party consultation for the testing proposals from 22 June 2017 until 7 August 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **3 November 2017**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019.

2. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.