EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114302871-57-01/F Helsinki, 30 June 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 1,3-diethyl-2-thiourea, CAS No 105-55-5 (EC No 203-308-5), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 1,3-diethyl-2-thiourea, CAS No 105-55-5 (EC No 203-308-5), submitted by [redacted] (Registrant).

- *Daphnia magna* reproduction test, OECD 211;
- Sediment-water *Lumbriculus* toxicity test, OECD 225.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 15 January 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 21 August 2013.

On 28 October 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 5 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 15 January 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 20 February 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 2015, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. In addition, the Registrant provided comments on the draft decision, concerning a request for extending the deadline for testing. The Member State Committee took the comments on the proposal for amendment of the Registrant and the deadline into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 7 April 2015 in a written procedure launched on 26 March 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225);

Note for consideration by the Registrant:

The Registrant 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 of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **9 January 2017** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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 aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

The Registrant has submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, EU C.20/OECD 211 with the following justification: *"The hazard assessment and the risk characterisation are currently based on acute aquatic toxicity data. In accordance with REACH Annex IX, column 2, "long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms". As the chemical safety assessment for the substance indicates the need for further testing, a long-term test on aquatic invertebrates is proposed in order to refine the PNEC value".* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

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

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation. Nevertheless, according to Article 12(1) and Annex VI to the REACH Regulation, its Annexes VI to XI stipulate minimum information requirements, and for each registration the precise information requirements will differ under consideration of the Annexes as a whole and the overall requirements of registration, evaluation and duty of care.

The Registrant has submitted a testing proposal for testing the registered substance for long-term toxicity testing on sediment organisms Sediment-water *Lumbriculus* toxicity test using spiked sediment (OECD 225). Although the current registration dossier concerns a substance manufactured in quantities of 100 – 1000 tonnes per year, the Registrant has indicated a need to generate this information with the following justification: *"As the exposure assessment indicates the need to investigate further the effects on sediment organisms, a long-term testing on sediment is proposed".*

ECHA notes that in absence of sediment toxicity information the Registrant has used the Equilibrium Partitioning Method to derive a PNEC sediment screen. In the risk characterisation (here in Section 9 of the CSR) the PNEC sediment screen has been used to assess the risks of the substance to sediment organisms. In Exposure scenario 1 the resulting risk characterisation ratio (RCR) is above 1 (RCR is [redacted]) indicating that risks to sediment do occur. ECHA notes that as the chemical safety assessment has indicated the need, the Registrant has accurately proposed to study the effects on sediment organisms.

The Registrant in his comments to the proposal for amendment agrees with the Competent Authority Member States' proposal for amendment that long-term toxicity to sediment organisms is not a standard information requirement in Annex IX; the long-term testing on sediment is only proposed by the Registrant because the exposure assessment and the PNECs derived by EPM indicates the need to investigate further the effects on sediment organisms (RCRsed>1).

ECHA considers that the proposed study is appropriate to further investigate long-term toxicity to sediment organisms (Annex X, Section 9.5.1. of the REACH Regulation).

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225).

Deadline for submitting the required information

The deadline granted for the update of the dossier for the above requested information is nine months to undertake the tests in parallel. However, based on the Registrant's comments on the draft decision (which were submitted with the Registrant's comments on the proposal for amendment), that "the RCRsed will certainly change after completion of the long-term testing to aquatic invertebrates, the decision to perform long term toxicity testing to sediment organisms should be taken after long-term toxicity testing to aquatic organisms is completed". The Registrant proposes to first test the long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.), to re-calculate the aquatic PNEC using the EPM method and consequently to re-calculate the RCRs and depending on the outcome, to then determine if a long-term toxicity to sediment organisms is required. The Registrant requests an extension of the deadline from nine months to 18 months to allow the testing, first the long-term toxicity testing on aquatic invertebrates and then, if the results of the chemical safety assessment indicate a need to investigate further, perform the long-term toxicity to sediment organisms. ECHA considers that as per the 'Note for consideration by the Registrant' in section II above, "the Registrant 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 of the REACH Regulation" and therefore ECHA agrees to the extension of the deadline to 18 months.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Claudio Carlon
Head of Unit, Evaluation