EUROPEAN CHEMICALS AGENCY

Helsinki, 5 December 2017

Addressee [redacted]

Decision number: TPE-D-2114381458-38-01/F
Substance name: 1,3-bis(3-methyl-2,5-dioxo-1H-pyrrolinylmethyl)benzene
EC number: 412-570-1
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04/05/2017
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 on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**
2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.**
3. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208) 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 **12 February 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 Kevin Pollard, Head of Unit, Evaluation E1

[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 to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)**

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You, as the Registrant, must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by you, the Registrant, instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "long-term toxicity to invertebrates" 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 a long-term toxicity test to invertebrates (*Earthworm Reproduction Test(Eisenia Fetida/Eisenia Andrei)*, OECD TG 222.

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days (or by default substances that are not readily biodegradable if no half-life is available) are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance is considered not readily biodegradable and no half-life in soil is available. Therefore, ECHA considers that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1., column 2.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. ECHA considers that you have chosen the Earthworm Reproduction Test (OECD TG 222) as the most appropriate one for the registered substance.

In your comments to the draft decision, you agreed to perform the requested test.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (OECD TG 222).

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You, as the Registrant, must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have submitted a testing proposal for the effects on soil micro-organisms (*Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216).

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals.

In your comments to the draft decision, you agreed to perform the requested test.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

3. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You, as the Registrant, must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by you instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity to terrestrial plants (*terrestrial Plant Test: Seedling Emergence and Seedling Growth Test*, OECD TG 208).

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days (or by default substances that are not readily biodegradable if no half-life is available) are considered very persistent in soil. The substance is not readily biodegradable and ECHA notes that no half-life in soil is available.

ECHA further notes that, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), the substance would fall into soil hazard category 4. For such substances it is not possible to adapt the present standard information requirement depending on the results of the other long-term study for soil requested by the present decision and an initial screening assessment based upon the Equilibrium Partitioning Method (EPM). The Guidance foresees that long-term toxicity tests should be carried out and that the lowest value obtained should be used to derive PNEC soil.

Finally, ECHA Guidance on information requirements and chemical safety assessment Chapter R10, section R.10.6.2. (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study, which ECHA accepted under point (1) above. Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on plants, and not the short-term, will provide the necessary information.

Therefore, ECHA agrees that a long-term testing is needed and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3., column 2.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocot species and four dicot species, selected according to the criteria indicated in OECD test guideline 208. You should consider if testing on additional species is required to cover the information requirement.

In your comments to the draft decision, you agreed to perform the requested test.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed study using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocot species and four dicot species).

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 18 months in order to reach as target date the 4th of January, 2019.

You justified this request by providing, as justification document, a laboratory statement providing that the work can be started in May 2018, and "*the draft reports can be expected in October 2018".* ECHA agrees that the deadline should, in any case, not be before the laboratory can provide the results of the tests.

Further, you sought to justify your request by stating that the expected "*additional effort to update the dossier, including exposure and risk characterisation*". Moreover, their "*providers tell them that they are also extremely busy with the preparation of the REACH 2018 period. Additional workload could lead to failure of the deadline for new registrations."*

ECHA agrees that the update of the dossier requires time and considers three months as appropriate to complete this task, but notes also that the REACH registration deadline is on 31 May 2018, while the laboratory has stated that "*the draft reports can be expected in October 2018"*. A deadline for the update in January 2019 takes this into account. Therefore, ECHA does not see this second argument to be fully substantiated. Furthermore, no justification document from your providers has been included to confirm this statement.

Therefore, ECHA has partially granted the request and set the deadline to 14 months in order to accommodate the request for having time until early January 2019.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 4 May 2017.

This decision does not take into account any updates after 11 September 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. 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.

2. 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.

3. 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.