EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114313205-65-01/F Helsinki, 11 December 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 3a,4,7,7a-tetrahydro-4,7-methanoindene, EC No 201-052-9 (CAS No 77-73-6), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 3a,4,7,7a-tetrahydro-4,7-methanoindene, EC No 201-052-9 (CAS No 77-73-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

ECHA notes that the information requirement of Annex VII/IX/X, section 8.4, has not been addressed in this compliance check. This specific information requirement was addressed in a previous compliance check decision (decision number CCH-D-0000003871-72-03/F).

The compliance check was initiated on 5 August 2015.

On 11 September 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 October 2015 ECHA received comments from the Registrant. In his comments the Registrant indicated that he intended to provide the requested information.

The ECHA Secretariat considered the Registrant's comments. As a result, ECHA amended the deadline in section II (Information required) of the draft decision. Section III (Statement of Reasons) was changed to reflect the Registrant's comments.

On 29 October 2015, ECHA notified the competent authorities of the Member States of its draft decision and invited them to propose amendments to the draft decision under Article 51 of the REACH Regulation.

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

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Composition of the substance (Annex VI, Section 2.3.)

B. Information related to robust study summaries that were already provided

Pursuant to Articles 41(1), 41(3), and 10(a)(vii) of the REACH Regulation the Registrant shall submit robust study summaries for the following endpoints:

2. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.);

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).

C. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

4. Viscosity (Annex IX, Section 7.17.; test method: OECD 114; at 40 °C);

5. Effects on terrestrial organisms – Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil, OECD 232);

6. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

D. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

7. Revised PNECs for freshwater, marine water, intermittent releases, microorganisms in sewage treatment plants, freshwater sediment, marine sediment and soil and re-assessment of related risks or a full justification for not using the recommendations of ECHA guidance in PNEC derivation (Annex I, section 3.3.1.), as specified under section III.D below;

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 request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

E. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA an update of the registration dossier containing the information specified in **sections II.A and II.B** of this decision by **18 March 2016** including, where relevant, an update of the Chemical Safety Report.

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA an update of the registration dossier containing the information specified in **sections II.C and II.D** of this decision by **19 December 2016** including, where relevant, an update of the Chemical Safety Report.

Note for information to the Registrant:
The substance 3a,4,7,7a-tetrahydro-4,7-methanoindene, EC No 201-052-9 (CAS No 77-73-6), is included on the community rolling action plan (CoRAP) update for years 2015–2017 (published on 17 March 2015) to be addressed under substance evaluation in 2016, in accordance with the procedure set out in Articles 44 to 48 and in Article 52 of the REACH Regulation. Two different deadlines are set in this decision, to allow sufficient time for conducting new tests while still ensuring that the information requested under sections II.A and II.B is available in an early phase of the substance evaluation process.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Composition of the substance (Annex VI, Section 2.3.)

Annex VI, section 2.3 of the REACH Regulation requires that the registration dossier contains adequate and sufficient information to enable the composition of the substance to be identified. In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014), the Registrant shall note that normally, impurities present in a concentration ≥ 1 % should be specified. However, impurities that are relevant for the classification and/or for PBT assessment shall always be specified, irrespective of the concentration. As a general rule, the compositional information should be completed up to 100 % and each constituent present requires a complete chemical specification.

The Registrant identified the registered substance as a well-defined mono-constituent substance "3a,4,7,7a-tetrahydro-1H-4,7-methanoindene" and specified a minimum concentration of [redacted] % (w/w) for the main constituent. However, the Registrant did not report any impurities in the composition.

ECHA notes that up to [redacted]% (w/w) of the composition has not been accounted for as the minimum degree of purity given is [redacted] % (w/w) and impurities have not been reported.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

The Registrant is accordingly requested to correct the information provided on the composition of the registered substance and report the missing [redacted]% (w/w).

If the substance is manufactured in different grades with differing impurity profiles, the composition of each grade shall be reported in IUCLID section 1.2. In addition analytical data shall be provided for each grade in IUCLID section 1.4.

Regarding how to report the composition in IUCLID, the following applies:
The Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2.

For each constituent the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.
For a group of constituents a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.
Further technical details on how to report the composition in IUCLID are available in paragraph 2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

If the Registrant reports different grades in IUCLID section 1.2, analytical data shall be reported for each grade in IUCLID Section 1.4.

B. Information related to robust study summaries that were already provided

According to Article 3(28) of the REACH Regulation, a robust study summary means "a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report"[1]. For the endpoints listed below, the data on test conditions, results and/or conclusions were not sufficient to make an independent assessment of the study and thus did not meet the requirements of a robust study summary within the meaning of Article 3(28). The Registrant is requested to provide the data according to Article 3(28) as outlined below.

2. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

The robust study summary for the key study "[redacted]" does not contain sufficient details in the sections 'Results and discussions' and 'Results and examinations'. For instance, data should be given showing, for each test group, body weight and body weight changes, food/water consumption, toxic response (including fertility, gestation, and any other signs of toxicity), functional assessments (sensory activity, grip strength and motor activity assessments, if available), haematological and clinical biochemistry findings, organ weights and organ/body weight ratios, histopathology findings, gestation details (including information on the number of implantations, abortions, early deliveries, stillbirths, resorptions, dead fetuses, corpora lutea). The data on the pups should include, for each test group, mean number and percent of live pups, sex ratio, body weight (by sex and with sexes combined), malformations and other relevant alterations.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit appropriate information on the key screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1).

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

The robust study summary for the key study "[redacted]" does not contain sufficient details in the sections 'Administration/Exposure', 'Results and discussions' and 'Results and examinations'. Information should be given outlining the rational for dose level selection. In addition, data should be given showing, for each test group, body weight and body weight changes, food/water consumption, toxic response (including fertility, gestation, and any other signs of toxicity), organ weights and organ/body weight ratios, gestation details (including information on the number of implantations, abortions, resorptions, live and dead fetuses, corpora lutea). The data on the fetuses should include, for each test group, sex ratio, body weight (by sex and with sexes combined), malformations and other relevant alterations.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit appropriate information on the key pre-natal developmental toxicity study (Annex IX, Section 8.7.2).

[1] For further information, please see ECHA Practical Guide 3 "How to report robust study summaries", version 2.0, November 2012.

C. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

4. Viscosity (Annex IX, Section 7.17.)

"Viscosity" is a standard information requirement as laid down in Annex VII, Section 7.17. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is that the substance is a waxy solid and therefore in accordance with REACH Annex XI, testing does not appear scientifically necessary. The Registrant's statement that "testing does not appear scientifically necessary", could be seen as a reference to Annex XI, section 1 (Testing does not appear scientifically necessary). However, the justification provided by the Registrant ("the substance is a waxy solid") is not considered relevant for any of the general rules for adaptation outlined in Annex XI, section 1, which addresses use of existing data, weight of evidence, qualitative or quantitative structure-activity relationship ((Q)SAR), in vitro methods and grouping of substances and read-across approaches.

Even if the argument provided by the Registrant would instead be interpreted as an attempt to adapt the information requirement in accordance with Annex XI, section 2 (Testing is technically not possible), ECHA considers that the adaptation by the Registrant does not meet the general rules for this adaptation. For testing of viscosity, the substance needs to be in a liquid (or liquid-like) state. As outlined in the ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7a, Version 4.0, July 2015), one viscosity value is preferably measured at approximately 20 °C and another at an approximately 20 °C higher temperature. Based on the melting point of 32.2 °C reported by the Registrant, the registered substance is in a solid state at 20 °C. It is thus likely that the viscosity cannot be measured at this temperature. However, the registered substance is expected to be in a liquid state at approximately 40 °C and it should thus be possible to measure the viscosity at this higher temperature. It is also noted that the classification criteria for aspiration hazard refer to kinematic viscosity at 40 °C. ECHA considers that information on the viscosity of the registered substance at 40 °C is relevant for the understanding of the properties of the registered substance and as a basis for classification of aspiration hazard.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Viscosity of liquids (test method: OECD 114) at 40 °C.

5. Terrestrial invertebrates (Column 2 of Annex IX, Section 9.4. and Annex X, Section 9.4.4.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.
The Registrant has waived the standard information requirements of Annexes IX and X, section 9.4. by arguing that in accordance with column 2 of REACH Annex X, the long term toxicity testing studies do not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects of the substance and/or degradation products on terrestrial organisms.

Based upon the available harmonised classification as Aquatic Chronic 2 (Toxic to aquatic life with long-lasting effects) 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), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

According to the evidence presented within the Registration dossier, the substance is considered as very persistent in soil. Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.
ECHA notes that long-term tests are suitable to simultaneously address the information requirements of section 9.4. of Annexes IX and X.

Therefore, the adaptations cannot be accepted. As no further data have been provided, the information available in the technical dossier on this endpoint for the registered substance does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comments on the draft decision, the Registrant indicated that they do not consider there to be any significant exposure to soil, and that testing on terrestrial invertebrates should not be necessary. The Registrant nevertheless indicated that a test will be conducted to address this information requirement. ECHA notes that the registration dossier does not contain any evidence or documentation that would indicate that direct or indirect exposure to the soil compartment is unlikely.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 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.

Pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is therefore requested to submit the following information derived with the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

The Registrant has waived the standard information requirement of Annex IX, Section 9.4.2. using the following justification: "*In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms.*"

Based on the agreement in the Member State Committee meeting MSC29, ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

Therefore, the adaptations cannot be accepted. As no further data have been provided, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comments on the draft decision, the Registrant indicated that they do not consider there to be any significant exposure to soil, and that testing on soil micro-organisms should not be necessary. The Registrant nevertheless indicated that a test will be conducted to address this information requirement. ECHA notes that the registration dossier does not contain any evidence or documentation that would indicate that direct or indirect exposure to the soil compartment is unlikely.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

Note for consideration by the Registrant
In relation to the calculation of the PNECscreen, which is to be used with the Equilibrium Partitioning Method (EPM), the Registrant should first comply with the request outlined in Section III.D below, in relation to the re-calculation of the PNEC for the aquatic compartment based on experimental aquatic toxicity data.

D. Information related to chemical safety assessment and chemical safety report

7. Revised PNECs for freshwater, marine water, intermittent releases, microorganisms in sewage treatment plants, freshwater sediment, marine sediment and soil and re-assessment of related risks or a full justification for not using the recommendations of ECHA guidance in PNEC derivation (Annex I, section 3.3.1.)

The Registrant derived the PNECs for freshwater, marine water, intermittent releases and microorganisms in sewage treatment plants by using the equation that underlies the PETROTOX model. A log Kow of 4.35 calculated with the SPARC model and a molecular weight of 132.21g/mole were used as input parameters. The PNECs for freshwater sediment, marine sediment and soil were derived using the equilibrium partitioning method. The aquatic PNEC was used together with the log Koc of 3.225 as input parameters.

ECHA notes that in the registration dossier the Registrant has provided results from experimental studies for aquatic toxicity; these have been combined in a weight of evidence approach, the outcome of which confirms the existing harmonised classification and labelling EC50 value of 4.4 mg/l. As outlined in the Guidance on information requirements and chemical safety assessment, Chapter R.10: "*Characterisation of dose [concentration]-response for environment*" (version 1, May 2008), experimental data should be used instead of predictions, when available.

ECHA also notes that the PETROTOX model is generally used for UVCB substances and the registered substance is a mono-constituent. Furthermore, it is unclear how the Registrant obtained the log Koc value of 3.225 as the Registrant has proposed to waive the information requirement for adsorption/desorption on the basis of the low potential for accumulation indicated by the log Kow of 2.78; additionally, he also provided two calculated predictions and proposes to use the value of 3.18 for the chemical safety assessment.

Therefore, pursuant to pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to recalculate all the PNECs starting using the experimental data available for aquatic toxicity.

E. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the information on viscosity, long-term toxicity testing on terrestrial invertebrates, effects on soil micro-organisms and revised PNECs was 9 months from the date of adoption of the decision. In his comments on the draft decision, the Registrant requested an extension of the timeline to 18 months. He sought to justify this request by overall workload and the large number of companies involved. ECHA considers that the Registrant's request is not sufficiently substantiated and concludes that an extension to 18 months is not warranted. ECHA however acknowledges that some extra time may be needed due to the high number of joint submission members and considers an extension of three months appropriate. Therefore, ECHA has partially granted the request and set the deadline for providing the requested information on viscosity, long-term toxicity testing on terrestrial invertebrates, effects on soil micro-organisms and revised PNECs to 12 months.

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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.

Authorised[2] by Ofelia BERCARU, Head of Unit, Evaluation E3

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