EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288847-27-01/F Helsinki, 18 November 2014

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

For tricyclodecanedimethanol, CAS No 26896-48-0 (EC No 248-096-5), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for tricyclodecanedimethanol, CAS No 26896-48-0 (EC No 248-096-5), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Sections 9.4 of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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 submitted after 4 September 2014, 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 26 March 2014.

On 11 July 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.

On 25 July 2014 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 4 September 2014 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier regarding effects on terrestrial organisms

Pursuant to Articles 41(1), 41(3), 10(a)(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:

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

2. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030); and

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

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **25 May 2016**. The timeline has been set to allow for sequential testing as appropriate.

C. 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 sound 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 Authorities of the Member States for enforcement.

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.

Pursuant to Articles 10(a)(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, VIII, IX, and X of the REACH Regulation.

"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.

1. Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justification:

"*In accordance with column 2 of REACH Annexes IX and X No 9.4, terrestrial studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Direct exposure to soil is not likely, since the substance is not intentionally applied to soil. According to the chemical safety assessment indirect exposure to soil is also not likely. The substance has a low vapour pressure and a low adsorption potential (log Koc < 3). The substance will not hydrolyse in contact with water. Therefore no hydrolysis products have to be assessed. In conclusion no testing is required. The equilibrium partitioning method will be applied to assess the hazard to soil organisms.*"

In his proposed adaptation the Registrant claims that exposure to soil is unlikely. However, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded e.g. Environmental Release Category (ERC) 8d, and also that the exposure estimations provided by the Registrant in the Chemical Safety Report (CSR) indicate that there is exposure to soil in a number of developed exposure scenarios. ECHA therefore considers that the Registrant has not demonstrated that soil exposure is unlikely.

ECHA further notes that the Registrant also indicates that the Registrant uses the Equilibrium Partitioning Method (EPM) to assess the hazard to soil organisms.

The Registrant seems to consider that with the EPM alone registrants could waive all five standard information requirements for effects on terrestrial organisms. However, the provision does not state that the EPM alone is sufficient to justify the adaptation of the standard information requirements. The second subparagraph of that Column 2 provision needs to be read in its entirety. Its aim is to establish whether there is a possibility to waive some of the standard information requirements stemming from Column 1 of Annex IX, 9.4. In order for an adaptation of the Column 1 provisions to be justified, registrants would have to demonstrate by means of the CSR that the conditions of an adaptation possibility in Column 2 or Annex XI are fulfilled. In establishing this, in some cases, registrants may use the EPM. Upon such a basis, registrants can then depending on the case establish whether some taxonomic group(s) could be waived.

In this context registrants have to take into account the other relevant provisions in Column 2 of Annex IX. The last sub-paragraph of that provision states that when a substance has a high potential to adsorb to soil or is highly persistent, even for registrations at a tonnage level between 100 up to 1000 tonnes long-term testing shall be considered instead of short-term testing. For registrations at a tonnage level of 1000 tonnes this is a standard information requirement.

In this specific case, ECHA notes that the Registrant has not justified an adaptation pursuant to Column 2 or Annex XI. A statement that the EPM leads to an RCR below 1 does not fulfil the conditions of any adaptation rule in REACH. ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to soil organisms (Annex XI, 1.2.). In fact, based on the information available in the dossier on the environmental fate 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 1.1., November 2012), ECHA considers that there is indication for high persistence of the substance in soil. According to the abovementioned section of the ECHA Guidance, substances with a half-life >180 days are considered very persistent in soil, and the Guidance further specifies that this should be the default setting in the absence of a DT_{50} <180 days unless the substance is classified as readily biodegradable. According to the evidence presented within the Registration dossier, the substance is not readily biodegradable and as no appropriate half-life for degradation in soil is presented, ECHA considers that there is indication for high persistence of the substance in soil. According to the abovementioned section of the Guidance, the EPM is not sufficient to assess the hazard to soil for substances for which there is indication for high persistence in soil. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

In his comments to the draft decision the Registrant claimed further that: "*All exposure assessments for all uses in life cycle included in the CSR show a PEC/PNECscreen << 1. The exposure scenarios leading to relevant environmental descriptors (ERC 8d and 8a) are used with tonnages of* [redacted] *t/a or less, each giving a RCR* [redacted] *using default settings. Taking into account both annual quantities and the very low RCRs we believe the submitted data demonstrate sufficiently, that exposure to soil is indeed unlikely.*"

ECHA understands that the Registrant is trying to make two arguments which should be kept separate: one relating to low risk and the other to low exposure. As explained above ECHA does not consider the Risk Characterisation Ratio (RCR) valid due to lack of a valid Predicted No Effect Concentration (PNEC). With regards to the exposure argument, ECHA notes the low tonnages, however, also the wide dispersive use (ERCs 8a and 8d) and concludes that the Registrant has not demonstrated that exposure is unlikely.

Based on the indication for high persistence in soil, ECHA notes that even if the substance was only registered at a tonnage of 100 to 1000 tonnes, long-term testing instead of short-term testing should have been considered.

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. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

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:

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).

In his comments the Registrant proposed to perform the earthworm reproduction test (OECD 222) as the first long-term soil toxicity test. As indicated in the point 4 below, ECHA is giving the Registrant the option to apply the integrated testing strategy (ITS) and to choose which long-term test to start with (eitherinvertebrates or plants). ECHA agrees that the Registrant can start with the earthworm reproduction test (OECD 222).

2. Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justification:

"*In accordance with column 2 of REACH Annexes IX and X No 9.4, terrestrial studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Direct exposure to soil is not likely, since the substance is not intentionally applied to soil. According to the chemical safety assessment indirect exposure to soil is also not likely. The substance has a low vapour pressure and a low adsorption potential (log Koc < 3). The substance will not hydrolyse in contact with water. Therefore no hydrolysis products have to be assessed. In conclusion no testing is required. The equilibrium partitioning method will be applied to assess the hazard to soil organisms.*"

As it is explained above under III.1., the information available on these endpoints 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 short- and long-term toxicity on terrestrial plants.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

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:

Terrestrial Plant Test: Seedling Emergence and Seedling Growth (test method: OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

Registrant in his comments on the draft decision indicated that: "*According to guidance r7c, Table R.7.11-2 further testing depends on the outcome of the long-term earthworm test: If PEC/PNEC screen < 1 and no indication of risk from confirmatory long-term soil toxicity testing: No further toxicity testing for soil organisms need to be done.* Any decision of further testing *therefore should be made based on the outcome of the long-term earthworm test.*"

As indicated in Section III part 4 below, ECHA is giving the Registrant the option to apply the integrated testing strategy (ITS) and to choose which long term-test to start with (either invertebrates or plants). Based on the results the Registrant may then wish to adapt the other information requirement if possible.

3. Soil micro-organisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. The registration dossier does not contain data for this endpoint. Instead, the Registrant has proposed to adapt testing on effects on soil microorganisms using the following justification:

"*In accordance with column 2 of REACH Annexes IX and X No 9.4, terrestrial studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Direct exposure to soil is not likely, since the substance is not intentionally applied to soil. According to the chemical safety assessment indirect exposure to soil is also not likely. The substance has a low vapour pressure and a low adsorption potential (log Koc < 3). The substance will not hydrolyse in contact with water. Therefore no hydrolysis products have to be assessed. In conclusion no testing is required. The equilibrium partitioning method will be applied to assess the hazard to soil organisms.*"

As it is already explained above under III.1., 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 toxicity for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p115, 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).

In his comments the Registrant states: "*According to guidance r7c, Table R.7.11-2 further testing depends on the outcome of the long-term earthworm test: If PEC/PNEC screen < 1 and no indication of risk from confirmatory long-term soil toxicity testing: No further toxicity testing for soil organisms need to be done. Any decision of further testing therefore should be made based on the outcome of the long-term earthworm test.*"

ECHA emphasizes that as mentioned below under point 4, the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the ECHA Guidance (based on EPM and other data that is available for the substance) does not apply for the endpoint of Annex IX, Section 9.4.2). Therefore ECHA considers it not possible to adapt this standard information requirement based on results of the study(ies) requested under points 1 and 2 above.

4. Notes for consideration by the Registrant

As stated above, based on the information currently available in the technical dossier on the environmental fate, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), ECHA considers that there is indication for high persistence of the substance in soil. 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. This means that once the results of one of the requested long-term soil toxicity tests ((1) or (2) above) as well as the results from the toxicity test on soil microorganisms ((3) above) have become available the Registrant may be able to justify an adaptation of the other requested long-term soil toxicity test ((1) or (2) above). Specifically he could examine whether or not screening assessment based on PNEC for soil organisms (derived by using EPM) indicates the risk to soil compartment when compared to relevant environmental concentrations in soil and whether or not performed toxicity tests with terrestrial organisms indicate a risk to the tested organisms. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly arguing why – out of weight of evidence considerations – taking into account the new information it is justified to adapt the information requirement for the second long-term soil toxicity test.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the Guidance (based on EPM and other data that is available for the substance) does not apply for the endpoint of Annex IX, Section 9.4.2).

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the studies 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, 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.

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