ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114297145-44-01/F Helsinki, 20 May 2015

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

For Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one, EC No 915-730-3, 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 Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one, EC No 915-730-3, submitted by [redacted] (Registrant). The scope of this compliance check 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 and other joint registrants 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 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.

The compliance check was initiated on 16 April 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. That draft decision was based on submission number [redacted].

On 18 August 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision requesting the long-term toxicity testing on plants and Effects on soil micro-organisms and comments for Long-term toxicity testing on terrestrial invertebrates.

On 18 August 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

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.

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 Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **29 February 2016**.

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 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 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 Annex IX of REACH (Regulation 1907/2006/EC), it is laid down that the choice of appropriate tests on soil organisms depends on the outcome of the chemical safety assessment. In the ECHA "Guidance on information requirements and chemical safety assessment – Chapter R.7c: Endpoint specific guidance" an Intelligent Testing Strategy is specified.
Although OTNE has a log Kow > 5, the log Koc is much lower than 5, i.e. 4.1. Furthermore OTNE is rapidly (but not readily) biodegradable with a DT50 in soil far below 180 days, i.e. 6.0 and 4.2 days in the sludge amended soil and in the agricultural soil respectively. There is therefore no indication for high adsorption or high persistence in soil. The aquatic toxicity data indicate that OTNE is not very toxic to aquatic organisms, all acute E(L)C50 values are >1 mg/l. Based on this information, the substance is assigned to soil hazard category 1 (Table R.7.11-2). The next step in the ITS is to perform the risk assessment for the soil compartment with a PNEC derived using the Equilibrium Partitioning Method (EPM). The risk assessment based on this PNECscreen reveals a PEC/PNEC ratio <1 for all life cycle stages. According to Table R.7.11-2 this means that no toxicity testing for soil organisms needs to be done.
Additional support for the reliability of the EPM for estimating the PNECsoil for OTNE is provided by the results for PNECsediment. The PNECsediment derived from studies on sediment organisms (3.7 mg/kg dw) did not deviate from the one based on equilibrium partitioning (3.5 mg/kg dw).

Based on the above, studies on the short and long-term effects on terrestrial invertebrates are waived."

The Registrant assigns the substance to soil hazard category 1 and uses the EPM to assess the hazard to soil. The Registrant's justification is, however, based on an erroneous

interpretation and selective reading of Column 2 of Annex IX, Section 9.4. The provision states:

> *"These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.*
> *In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment.*
> *In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall [explanatory note: already at the Annex IX tonnage level] consider long-term toxicity testing instead of short-term."* (emphasis added)

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 Chemical Safety Report (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, for the present substance ECHA disagrees with the Registrant that there would be no indication for high adsorption of the substance in soil or for indication for high toxicity to aquatic organisms. The Registrant states that the substance has a log Kow > 5. Thus, in accordance with section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012) the substance should be considered as highly adsorptive. The Registrant argues in his justification that the lower log Koc of 4.1 would indicate that the substance would not be highly adsorptive. However, as indicated by the ECHA Guidance Chapter R.7a section R.7.1.15. (version 2.4., February 2014), the soil sorption (Koc) of organic substances can often be estimated from their octanol-water partition coefficient (Kow). The abovementioned section of the ECHA Guidance gives reference to several publications on reviews of Koc prediction. Based on the equations given in i.e. Doucette, W.J. (2003) *Quantitative structure-activity relationships for predicting soil-sediment sorption coefficients for organic chemicals*. Environmental Toxicology and Chemistry 22, 1771-1778, a log Kow of 5 would correspond to log Koc values ranging from approximately 3 to 5 (with a mean value of approximately 4) for different chemical classes. ECHA therefore considers that a log Koc > 4 could be seen, in addition to a log Kow >5, as an indication of strong binding behaviour to soil particles.

The Registrant further argues in his justification that the substance is not very toxic to aquatic organisms because all acute E(L)C50 values are >1 mg/l. However, based on the 21-d NOEC reported for *Daphnia magna* of 0.028 mg/L, ECHA considers that the substance is very toxic to aquatic life. ECHA notices that the Registrant has also classified the substance as Aquatic Chronic 1 with the hazard statement H410: Very toxic to aquatic life with long lasting effects.

As explained above, ECHA considers that there are indications that the substance is very toxic to aquatic organisms and for high adsorption of the substance in soil. The EPM-method is, according to section R.7.11.6. of ECHA Guidance Chapter R.7c, not applicable for substances having these properties. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

Based on the indication for high adsorption 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.

In his comments on the draft decision and updated dossier the Registrant argues that: "With a Weight of Evidence the long-term toxicity information on sediment organisms, consisting of an insect, a worm and a benthic crustacean, will be used to address the toxicity to terrestrial invertebrates. It will be shown that a worm or arthropod study in soil is scientifically unjustified. For OTNE information on the long term toxicity of (macro-) invertebrates is available from the sediment. A sediment matrix is comparable to the soil matrix, except that the water content is high and the oxygen levels are lower. In both matrices, the likely routes of exposure are by diffusion from the pore water through the skin and by oral uptake. The behaviour of a test substance and the organisms in sediment and soil are similar and thus the toxic effects will be similar. Long-term information is available for sediment organisms for representatives of worms, insects and macro-crustaceans and as such we have covered a wide physiological spectrum. This means that relevant additional information is not expected and the study is therefore scientifically unjustified. The long-term toxicity information from the sediment will be used to fill the data requirements for soil invertebrates. This information will be converted to soil invertebrates using a correction for the organic carbon content in the sediment tests versus standard soil."

Essentially, the Registrant in his comments and updated dossier is using one line of weight of evidence stating that "the long-term toxicity information on sediment organisms, consisting of an insect, a worm and a benthic crustacean, is used to address the toxicity to terrestrial invertebrates."

ECHA notes that according to REACH Annex XI, section 1.2 a "sufficient weight of evidence approach needs to consist of several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property."

As the registrant only refers to one source and thus did not fulfil the requirements of Annex XI, section 1.2 ECHA cannot accept the weight of evidence argumentation.

Furthermore, as mentioned in the draft decision ECHA considers that there are indications that the substance is very toxic to aquatic organisms and that it has the potential for high adsorption in soil. The EPM-method is, according to section R.7.11.6. of ECHA Guidance Chapter R.7c, not applicable for substances having these properties and according to the guidance Table R.7.11-2, two long term toxicity tests according to the standard information requirements Annex X (invertebrates and plants) shall be performed and the lowest value shall be chosen for derivation of PNECsoil.

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).

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 Annex IX of REACH (Regulation 1907/2006/EC), it is laid down that the choice of appropriate tests on soil organisms depends on the outcome of the chemical safety assessment. In the ECHA "Guidance on information requirements and chemical safety assessment – Chapter R.7c: Endpoint specific guidance" an Intelligent Testing Strategy is specified.
Although OTNE has a log Kow > 5, the log Koc is much lower than 5, i.e. 4.1. Furthermore OTNE is rapidly (but not readily) biodegradable with a DT50 in soil far below 180 days, i.e. 6.0 and 4.2 days in the sludge amended soil and in the agricultural soil respectively. There is therefore no indication for high adsorption or high persistence in soil. The aquatic toxicity data indicate that OTNE is not very toxic to aquatic organisms, all acute E(L)C50 values are >1 mg/l. Based on this information, the substance is assigned to soil hazard category 1 (Table R.7.11-2). The next step in the ITS is to perform the risk assessment for the soil compartment with a PNEC derived using the Equilibrium Partitioning Method (EPM). The risk assessment based on this PNECscreen reveals a PEC/PNEC ratio <1 for all life cycle stages. According to Table R.7.11-2 this means that no toxicity testing for soil organisms needs to be done.
Additional support for the reliability of the EPM for estimating the PNECsoil for OTNE is provided by the results for PNECsediment. The PNECsediment derived from studies on sediment organisms (3.7 mg/kg dw) did not deviate from the one based on equilibrium partitioning (3.5 mg/kg dw).

Based on the above, studies on the short and long-term effects on terrestrial plants are waived."

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.

In his comments on the draft decision the Registrant accepts ECHA's view that the current dossier is incompliant for data on the terrestrial toxicity. The Registrant states that he intends to fulfill the data requirement by performing the study on plants. In his updated dossier the registrant has submitted a testing proposal for OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth). ECHA thus concludes that the registrant agrees to carry out the study requested in the draft decision. It also notes that no separate decision on the testing proposal will need to be issued as ECHA already requests this study by the present decision.

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).

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 Annex IX of REACH (Regulation 1907/2006/EC), it is laid down that the choice of appropriate tests on soil organisms depends on the outcome of the chemical safety assessment. In the ECHA "Guidance on information requirements and chemical safety assessment – Chapter R.7c: Endpoint specific guidance" an Intelligent Testing Strategy is specified.
Although OTNE has a log Kow > 5, the log Koc is much lower than 5, i.e. 4.1. Furthermore OTNE is rapidly (but not readily) biodegradable with a DT50 in soil far below 180 days, i.e. 6.0 and 4.2 days in the sludge amended soil and in the agricultural soil respectively. There is therefore no indication for high adsorption or high persistence in soil. The aquatic toxicity data indicate that OTNE is not very toxic to aquatic organisms, all acute E(L)C50 values are >1 mg/l. Based on this information, the substance is assigned to soil hazard category 1

(Table R.7.11-2). The next step in the ITS is to perform the risk assessment for the soil compartment with a PNEC derived using the Equilibrium Partitioning Method (EPM). The risk assessment based on this PNECscreen reveals a PEC/PNEC ratio <1 for all life cycle stages. According to Table R.7.11-2 this means that no toxicity testing for soil organisms needs to be done.
Additional support for the reliability of the EPM for estimating the PNECsoil for OTNE is provided by the results for PNECsediment. The PNECsediment derived from studies on sediment organisms (3.7 mg/kg dw) did not deviate from the one based on equilibrium partitioning (3.5 mg/kg dw).

Based on the above, a study on the effects on soil microorganisms is waived."

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.

In his comments on the draft decision the Registrant accepts ECHA's view that the current dossier is incompliant for data on the terrestrial toxicity. The Registrant states that he intends to fulfill the data requirement by performing the study on soil micro-organisms. In his updated dossier the registrant has submitted a testing proposal for Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216. ECHA thus concludes that the registrant agrees to carry out the study requested in the draft decision. It also notes that no separate decision on the testing proposal will need to be issued as ECHA already requests this study by the present decision.

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).

4. Notes for consideration by the Registrant:

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 by the Registrant and other joint registrants 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 and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

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.

[redacted]
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