

Helsinki, 7 July 2017

Addressee: [REDACTED]

Decision number: TPE-D-2114363752-46-01/F

Substance name: 1,1,3,3-TETRAMETHYLBUTYL 2-ETHYLPEROXYHEXANOATE

EC number: 244-894-2

CAS number: 22288-43-3

Registration number: [REDACTED]

Submission number: [REDACTED]

Submission date: 13.06.2016

Registered tonnage band: 100-1000T

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.**

You are additionally requested to perform:

- 2. 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.**
- 3. 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.**

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 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **14 January 2019**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. 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, shall 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>.

Authorised¹ by Ofelia Bercaru, Head of Unit, Evaluation E3

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 proposal(s) submitted by you.

1. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1. and column 2 of Annex IX, 9.4.)

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 and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: 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.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by 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 OECD Guideline 222) with the following justification: "*Based on the latest findings, including chronic daphnia, it can be concluded that 1,1,3,3-TETRAMETHYLBUTYL PEROXY2-ETHYL HEXANOATE is not hazardous to the aquatic compartment and no PNEC aquatic was derived. Consequently, EPM can not be used to calculate PNEC soil. Hence, there is a need to generate soil data. An OECD 222 (earthworm reproduction test) is planned*". 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 are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($\log K_{ow}$ 6.2) and therefore ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.1.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222.

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

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

“Effects on terrestrial organisms” is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: 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.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by 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 plants” is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The proposed test accepted by ECHA under point (1) above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

You have proposed to adapt this standard information requirement by “*A long term study to soil invertebrates is planned (OECD 222). The need of test on other terrestrial organisms will be evaluated after the outcome of the risk assessment to be performed with the planned OECD 222 data*”.

You have considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

Moreover, ECHA considers that only a long-term toxicity test on plants will provide the necessary information on the properties of the substance. At this tonnage level, according to column 2 of Section 9.4. of Annex IX, the registrant shall consider long-term testing for substances that have a high potential to adsorb in soil or that are very persistent. Based on the substance properties as discussed under point (1) above, there is an indication for high adsorption potential (logKow of 6.2) of the substance in soil. That indicates the need for long-term testing to be performed. You did also not provide any argument why long-term testing would not be appropriate.

It is also noted that the *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 tests 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. For all these reasons, ECHA concludes that, only a long-term toxicity test on plants (and not the short-term) will provide the necessary information.

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 monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out one of the following additional studies 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 monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

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

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. 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.).

The information on "effects on soil micro-organisms" 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 proposed to adapt this standard information requirement by "*A long term study to soil invertebrates is planned (OECD 222). The need of test on other terrestrial organisms will be evaluated after the outcome of the risk assessment to be performed with the planned OECD 222 data*".

ECHA notes that the proposed test that ECHA accepted under point (1) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test. 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, such as the registered substance. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

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

Notes for your consideration

ECHA notes that there is an information gap identified in the technical dossier of the registered substance for the standard information requirement of Long-term toxicity to fish (Annex IX, Section 9.1.6.) as described in the compliance check draft decision number [CCH-D-2114345358-44-01/D]. Consequently, currently there is no sufficient evidence to show the absence of effects in aquatic compartment.

After the results of the long-term aquatic study on fish become available, you can refine your terrestrial testing strategy. If the results of the aquatic toxicity test on fish allow the subsequent derivation of a PNEC_{water} you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the *ECHA Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014).

In the case of absence of effects in aquatic compartment, ECHA in Chapter R.7c of its *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014) advocates a *Weight-of-Evidence* approach to modify/waive the data requirements of Annex IX and X where a single soil test on a suitable species would be adequate to meet the requirements of Annex IX. Where the substance is highly adsorptive ($\log K_{ow}/K_{oc} > 5$), and/or the substance is very persistent in soil, this single test should be a long-term test.

If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, section 9.4. of the REACH Regulation.

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 9.4.3. does not apply for the present endpoint.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 23 March 2016 (submission number [REDACTED]).

This decision does not take into account any updates after **3 January 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:

On 21 October 2016 ECHA notified you of the draft decision and invited you to provide comments.

On 23 November 2016 ECHA received comments on the draft decision.

ECHA took into account your comments but did not amend the request(s), as ECHA considered your comments were not on the testing proposal draft decision requests but identical to your comments you submitted on the parallel compliance check draft decision, for the same registration dossier (Communication number: CCH-D-2114345358-44-01/D). Also, ECHA considered your comments were not relevant to the testing proposal draft decision requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You indicate in your comments on the proposed amendment(s) you have started to perform the Long-term toxicity on terrestrial invertebrates: Earthworm reproduction test, OECD TG 222) using the registered substance.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-54 written procedure and ECHA took the decision according to Article 51(6) 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 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.
3. In carrying out the test(s) 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 test(s) 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 test(s) to be assessed.