EUROPEAN CHEMICALS AGENCY

Helsinki, 20 September 2016

Addressee: [redacted]

Decision number: TPE-D-2114343931-50-01/F
Substance name: di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
EC number: 229-782-3
CAS number: 6731-36-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15.04.2015
Registered tonnage band: [redacted]

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your originally proposed test for Long-term toxicity on terrestrial invertebrates (Determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of *Caenorhabditis elegans* (Nematoda), ISO 10872:2010) is rejected.

You are requested to perform as additional test:

1. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220)) using the registered substance;**
2. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test (OECD TG 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)) 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 **27 September 2017**. 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.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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 submitted by you.

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

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. You must therefore 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.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and effects on soil micro-organisms (Annex IX, section 9.4.2.). 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.

You have submitted a testing proposal for a Determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of *Caenorhabditis elegans* (Nematoda), ISO 10872:2010 with the following justification: *"At this stage, although exposure to the soil is considered unlikely, it cannot be completely excluded. A study is therefore proposed."* 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 ($logK_{oc}$ equal 5.1 at 20 °C) and is considered very persistent which is default setting for not readily biodegradable substances, when a value of the half-life in soil is not available. Therefore, ECHA concludes that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX).

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 requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that according to the test guideline ISO 10872:2010 the guideline can be used *"for determining the toxicity of environmental samples on growth, fertility and reproduction of Caenorhabditis elegans".* The test guideline does not contain a description of the procedure for preparation of test sample by spiking of the soil by a substance of interest. Furthermore, there is a publication by Huguier *et al.* (Environmental Toxicology and Chemistry, Vol. 32, No. 9, pp. 2100–2108, 2013) where improvements to the *Caenorhabditis elegans* growth and reproduction test in soils are proposed. These proposals are not implemented in the current version of the test guideline. Therefore, ECHA considers that the results of this study would not be adequate for the purpose of classification/labelling and risk assessment.

Thus, ECHA concludes that the proposed test guideline ISO 10872:2010 is not designed for the testing of soil samples spiked by the substance of interest and cannot address REACH data requirement for the long-term toxicity testing with soil invertebrates.

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

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: Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2, test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222 or Enchytraeid reproduction test OECD 220.

Your originally proposed test for Long-term toxicity on terrestrial invertebrates (Determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of *Caenorhabditis elegans* (Nematoda), ISO 10872:2010) is rejected.

2. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 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 and X, Section 9.4. of the REACH Regulation. You must therefore 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.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and effects on soil micro-organisms (Annex IX, section 9.4.2.). 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.

ECHA notes that you have sought to adapt the long-term toxicity testing on terrestrial plants using the following justification: "*Based on the environmental exposure scenarios, and the fact that no terrestrial PNEC can be calculated using the Partition Equilibrium method as no aquatic effects have been found, chronic studies for sediment and water compartments have been conducted as these are expected to be the compartments most of concern. Furthermore there is no direct terrestrial application of this substance. Additional sewage treatment simulation testing is ongoing to establish if release to this compartment can be expected.*" ECHA notes that in the justification of the testing proposal with nematodes (discussed under point (1) above) you have stated that "*although exposure to the soil is considered unlikely, it cannot be completely excluded".* Furthermore, you have considered that it is not feasible, 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. Therefore, there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

The test required by ECHA under point (1) above is not sufficient by itself to address the standard information requirements 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 are indications for high adsorption potential and high persistence 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 requested 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.

Terrestrial plants, growth test (OECD 208) conducted with six 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) as the minimum to achieve a reasonably broad selection and Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial plants. 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 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. You must therefore address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have sought to adapt the information requirement for "effects on soil micro-organisms". You provided the following justification for the adaptation: "*Based on the environmental exposure scenarios, and the fact that no terrestrial PNEC can be calculated using the Partition Equilibrium method as no aquatic effects have been found, chronic studies for sediment and water compartments have been proposed as these are expected to be the compartments most of concern. Additional sewage treatment simulation testing is ongoing to establish if release to this compartment can be expected.*" ECHA notes that in the justification of the testing proposal with nematodes (discussed under point (1) above) you have stated that "*although exposure to the soil is considered unlikely, it cannot be completely excluded".* Furthermore, you have considered that it is not feasible, 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. Therefore, there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.2.

ECHA notes that the test that ECHA requested 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.

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.

4. Deadline to submit the requested information

In the draft decision communicated to you the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 12 months. You sought to justify this request by the argumentation that that the requested testing of the substance might be technically complicated as well as various tests requested might be run not in parallel. ECHA acknowledges your note that the substance is challenging for the testing requested. Therefore, ECHA has granted the extension and set the deadline to 12 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 15 April 2015.

This decision does not take into account any updates after **23 May 2016**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

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

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the 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 relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new test(s) 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.