ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114300117-67-01/F Helsinki, 18 June 2015

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

For 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol, CAS No 119-47-1 (EC No 204-327-1), 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 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol, CAS No 119-47-1 (EC No 204-327-1), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of 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 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.

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 30 April 2014.

On 10 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 31 July 2014 ECHA received comments from the Registrant on the draft decision.
On 19 September 2014 the Registrant updated his registration dossier (submission number [redacted]).

The ECHA Secretariat considered the Registrant's comments and update.
On the basis of this information, the Section II and the deadline in Section II were amended. The Statement of Reasons (Section III) was changed accordingly.

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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 20 February 2015 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did amend the draft decision.

On 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 7 April 2015 in a written procedure launched on 26 March 2015.

ECHA took the decision pursuant to Article 51(6) 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).

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 a derivation of the terrestrial PNEC.

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.

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 **2 January 2017**.

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:

"According to column 2 of REACh Regulation No. 1907/2006, Annex IX and X, tests on short- and long-term toxicity to "terrestrial organisms" shall be proposed by the registrant if the results of the chemical safety assessment indicate the need to investigate further effects of the substance and/or relevant degradation products on terrestrial organisms. Since this is not the case, the performance of a test on the toxicity of DBMC for the terrestrial organisms is not needed:

In the chemical safety assessment of DBMC, no risk to the soil compartment is identified for all relevant uses (PEC/PNEC < 1), so that a refinement of the PNECsoil on the basis of toxicity study with the soil is not required."

In his proposed adaptation the Registrant claims that no study on terrestrial organisms is needed since the Risk Characterisation Ratios are below 1 for all relevant uses. ECHA notices that the Registrant has derived the PNEC soil only based on the Equilibrium Partitioning Method (EPM) and with the use of a "theoretical" PNECaquatic.

According 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), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

The Registrant has 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 EPM and other data available on the substance. Furthermore, ECHA notes that the Column 2 provision referred to by the Registrant does not allow to adapt the standard information requirements on the basis that – taking into account currently available information – the RCR would be below 1 for all relevant uses. In order for the standard information requirements to be adapted, the Registrant would have to demonstrate that the conditions of an adaptation possibility in Column 2 of the relevant information requirement or in Annex XI are fulfilled. The Registrant has not provided such arguments.

Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

Furthermore, ECHA notes that according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), substances that are ionisable or have a log K_{ow} >5 are considered highly adsorptive. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 6.25). ECHA notes that, in order to consider the high potential to adsorb to soil, the tests shall be long-term.

In their comments the Registrant agreed to perform the requested test and also expressed this in the updated dossier where the Registrant has included the following: "REACh Regulation No. 1907/2006, Annex IX and X requires information on short-term toxicity to soil invertebrates. Long-term toxicity to "terrestrial organisms" shall be considered for substances that have a high potential to adsorb to soil or that are very persistent. With a Koc of 150000, a high potential to absorb is given for 6,6´-di-tert-butyl-2,2´-methylendi-p-cresol. The substance is not readily biodegradable and therefore considered as preliminary persistent. No effects have been observed in aquatic organisms up to the limit of the water solubility. Therefore, no PNECaqua could be derived. As a consequence, also no PNEC soil can be calculated using EPM. The substance has a Koc of 150000 which is extremely high. Such substances are mainly adsorbed to soil particles whereas the concentration in the pore water tends to zero.
The Registrant intends to perform a long term test in earthworm. Earthworms live mainly from soil particles and therefore the ingestion of adsorbed substance is highest thus representing the worst case for soil dwelling organisms. The study will only be started after ECHA has performed its final approval."

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:

"According to column 2 of REACh Regulation No. 1907/2006, Annex IX and X, tests on short- and long-term toxicity to "terrestrial organisms" shall be proposed by the registrant if the results of the chemical safety assessment indicate the need to investigate further effects of the substance and/or relevant degradation products on terrestrial organisms. Since this is not the case, the performance of a test on the toxicity of DBMC for the terrestrial organisms is not needed:

In the chemical safety assessment of DBMC, no risk to the soil compartment is identified for all relevant uses (PEC/PNEC < 1), so that a refinement of the PNECsoil on the basis of toxicity study with the soil is not required."

In their comments and updated dossier the Registrant has reasoned that the weight-of-evidence (WoE) approach outlined in ECHA Guidance R.7.c (Version 1.1., November 2012, p. 124) is applicable as the water solubility has been determined to be 0.007 mg/L and no effects were observed up to the limit of the water solubility in the acute tests.

The above mentioned ECHA's Guidance outlines that "where the water solubility is <1 mg/l, the absence of acute toxicity can be discounted as reliable indicator for potential effects on soil organism due to the low exposures in the test. The absence of chronic or long-term effects in aquatic organisms up to the substance solubility limit, or of acute effects within the solubility range above 10 mg/l can be used as part of a Weight of Evidence argument to modify/waive the data requirements of Annex IX and X".

Furthermore the Registrant in his comments expressed that: "If PEC/PNECsoil is not well below 1, a terrestrial plant test according to OECD 208 should be performed subsequently [after the long-term invertebrate test]." In the updated dossier the Registrant stated that: "A stepwise procedure is proposed: In case of measurable effects in the earthworm reproduction test a PNECsoil will be derived and the exposure estimations in the CSR will be updated considering latest information on tonnages and use conditions. If PEC/PNECsoil is well below 1, no further testing, e.g. in terrestrial plants, is considered necessary. In case of no effects in the earthworm reproduction test, no PNEC soil can be calculated."

ECHA notes that based on available information in the current technical dossier, the above weight-of-evidence (WoE) approach is not considered by ECHA as a scientifically justified adaptation, as the requirements of Annex XI section 1.2. are not fulfilled.

After the results of the earthworm study become available the Registrant may build a scientifically justified adaptation based on available information for example a WoE approach, the acceptability of which ECHA would evaluate during the follow up process of the present compliance check (Article 42 of the REACH Regulation).

ECHA has prolonged the deadline for submitting the requested information to 18 months in Section II.B of this decision to account for sequential testing.

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).

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.

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