EUROPEAN CHEMICALS AGENCY

Helsinki, 25 June 2019

Addressee: [redacted]

Decision number: CCH-D-2114471002-64-01/F
Substance name: 1,3-diisopropylbenzene
EC number: 202-773-1
CAS number: 99-62-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 03/05/2016
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure] with the registered substance;**

You have to submit the requested information in an updated registration dossier by **2 April 2020**. 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 and 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, has to 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, Hazard Assessment

[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.

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Appendix 1: Reasons

1. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

A Bioaccumulation in aquatic species study is a standard information requirement as laid down in Annex IX, Section 9.3.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have provided a study record for a OECD 305E Bioaccumulation: flow-through fish test (CERI) to meet the standard information requirement of Annex IX, Section 9.3.2.

ECHA Guidance on How to report robust study summaries, Practical Guide 3 (version 2.0 November 2012) and the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) explain what information needs to be provided in a robust study summary.

However, ECHA notes that, contrary to Article 3(28) of the REACH Regulation and what is described in the above mentioned guidances, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard and PBT assessment.

In particular, the following elements are missing: Fish lipid content, information on fish weight and growth during the conduct of the study, numbers of test fish, duration of the uptake and depuration phases, information on the analytical method and its sensitivity, information on sampling and information on temperature variation.

Further to this, ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) explains that for bioaccumulative substances the kinetics of bioaccumulation are slow and growth dilution may have a major impact on the bioconcentration factor (BCF). BCF K_{gL} (The lipid normalised, growth corrected kinetic bioconcentration factor) is preferred for PBT substances due to i) the slow kinetics possibly leading to non-equilibrium within the timeframe of the experimental bioaccumulation test, and especially ii) the correction for growth dilution, which is not included in the steady state BCF. The lipid normalised, growth corrected kinetic bioconcentration factor (BCF K_{gL}) is normalised to a fish with a 5% lipid

content and corrected for growth during the study period as described in Annex 5 of the OECD TG 305.

ECHA notes that information on the fish lipid content and growth is critical to inform the PBT assessment given that the results of the study indicate that there is bioaccumulation potential with BCF values ranging from 546 to 3210 at 2 µg/L m-Diisopropylbenzene (1,3-diisopropylbenzene).

ECHA issued a draft decision (Communication number: CCH-D-2114430328-53-01/D) on this dossier on 16 July 2018 requesting a robust study summary for the OECD 305E Bioaccumulation: flow-through fish test (CERI). In your comments on that decision you stated that additional information is not available for the 1983 BCF study on the mixture of the meta-and para-isomers and that therefore no update of the Robust Study Summary is possible. You further indicated your willingness to conduct a new BCF study following OECD Guideline 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible.

ECHA notes that the aqueous route of exposure is feasible given that the available OECD 305 (CERI) study from 1983 was conducted via this route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision
Bioaccumulation in fish: aqueous exposure bioconcentration fish test (test method: OECD TG 305-I)

Notes for your consideration

In your comments on the previous draft decision (Communication number: CCH-D-2114430328-53-01/D) you indicated your willingness to conduct a new BCF study following OECD Guideline 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure and requested approval from ECHA to conduct the new OECD 305 bioaccumulation study using a mixture of the meta and para isomers in order to reduce testing needs for other similar substances. ECHA notes that there are registrations for p-Diisopropylbenzene (EC 202-826-9) and also for Diisopropylbenzene (EC 246-835-6, which contains both m-Diisopropylbenzene and p-Diisopropylbenzene). ECHA notes that the OECD 305 (CERI) study from 1983 was conducted on a mixture of meta and para isomers of diisopropylbenzene and that it was

possible to determine BCF values for each isomer in that study. Accordingly, you can also consider to perform a single OECD 305 study on the analogue substance Diisopropylbenzene EC 246-835-6 (which contains both m-Diisopropylbenzene and p-Diisopropylbenzene) to fulfil this informaiton requirement. Please be informed that a decision requesting an OECD 305 study has also been sent to the registrant for that substance (EC 246-835-6). According to Article 25 of the REACH Regulation testing on vertebrate animal shall be undertaken only as a last resort. Therefore, in case you decide to perform the test on the mixture of meta and para isomers of diisopropylbenzene you will need to discuss with the Registrants of that substance and agree on who will perform the test and how best to fulfil the information gaps for both registations.

In your comments on this draft decision you explained that you discussed with the Registrant of Diisopropylbenzene (EC 246-835-6) how best to fulfil the information gaps for both registrations and agreed to perform an OECD 305, bioaccumulation in fish test. You indicate that the test will be performed with aqueous exposure and on the test substance diisopropylbenzene, mixture of isomers (25321-09-9; 246-835-6).

ECHA considers this to be appropriate to address the information gap.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 15 October 2018.

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

ECHA notified you of a Draft decision (CCH-D-2114430328-53-01/D) based on your dossier (Submission number: [redacted]; Submission date: 03 May 2016) on the 16 July 2018. After receiving your comments on that draft decision, ECHA decided to terminate that decision making process and issue a new draft decision.

ECHA notified you of this 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 request.

ECHA notified the draft decision to the competent authorities of the Member States for proposals 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. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2020.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of your Member State.

4. In carrying out the tests 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 tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.

5. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.